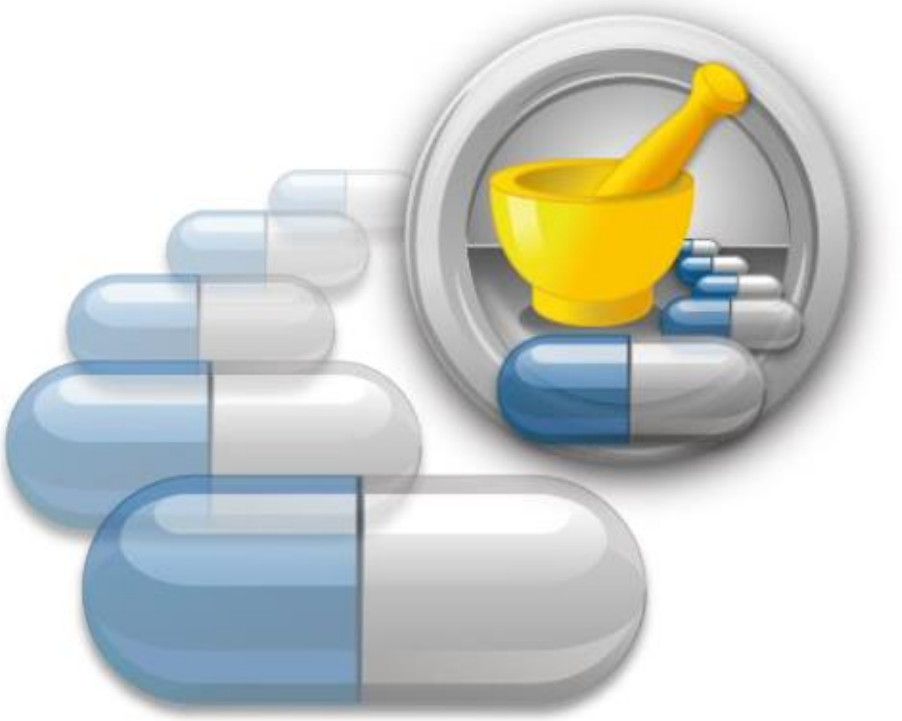
FT PharmaSuite®



IPC PHASES

RELEASE 11.01.00

FUNCTIONAL REQUIREMENT SPECIFICATION

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1 Introduction

This document details the requirements of the functions implemented by the phases specific to in-process control (IPC). The phases are either related to an event-triggered operation and executed in the Production Execution Client or to a server-run operation and executed on the Operation Execution server (OES) of PharmaSuite.

Each requirement is composed of a name (e.g., Preview mode) and a unique identifier (e.g., GID-1234567) and is extended with its business attributes (GxP Relevance, Business Impact) and its compliance attribute (21 CFR Part 11 Relevance).

For requirements with **Framework capability** as identifier, see "Functional Requirement Specification Execution Framework" for their unique identifier, [A1] (GID-2668005).

The revision history lists the changes made to the document with the previous FactoryTalk PharmaSuite release as the comparison baseline. It provides individual tables for "Updated", "Added", and "Deleted" requirements that juxtapose the previous approved version with the new approved version of an item.

Typographical Conventions

This documentation uses typographical conventions to enhance the readability of the information it presents. The following kinds of formatting indicate specific information:

Bold typeface	Designates user interface texts, such as ▪ window and dialog titles ▪ menu functions ▪ panel, tab, and button names ▪ box labels ▪ object properties and their values (e.g., status).
Monospaced typeface	Designates code examples.

2 IPC-related Phases and Operations

PharmaSuite for Production Execution uses event-triggered operations (ETOs) as templates to create specific runs (ETO instances), which then are executed by the operator.
The creation of the runs is triggered either manually by an operator or automatically by a trigger phase. This system behavior specifically supports In-process control (IPC)-related use cases, but it can also be applied to other use cases.

The typical structure of a recipe with an event-triggered operation can be modeled with the following characteristics:

- An operation with the **Event-triggered** capability represents an ETO.
  The runs can be created automatically by a trigger phase if the operation also holds the **Trigger-enabled** capability.
- For automatic triggers, the trigger phases are located in an operation that holds the **Server-run** capability. Thus, the operation and its phases are not visible in the Production Execution Client.
- Both the **ETO template** and the **Server-run operation with trigger phase** operations are located on parallel branches, which means both operations become active during execution at the same time.
- The **Trigger-enabled** capability allows to reference specific trigger phases that typically run on a server (within a server-run operation).
  One ETO can reference multiple trigger phases.
  One trigger phase can be referenced from multiple ETOs.

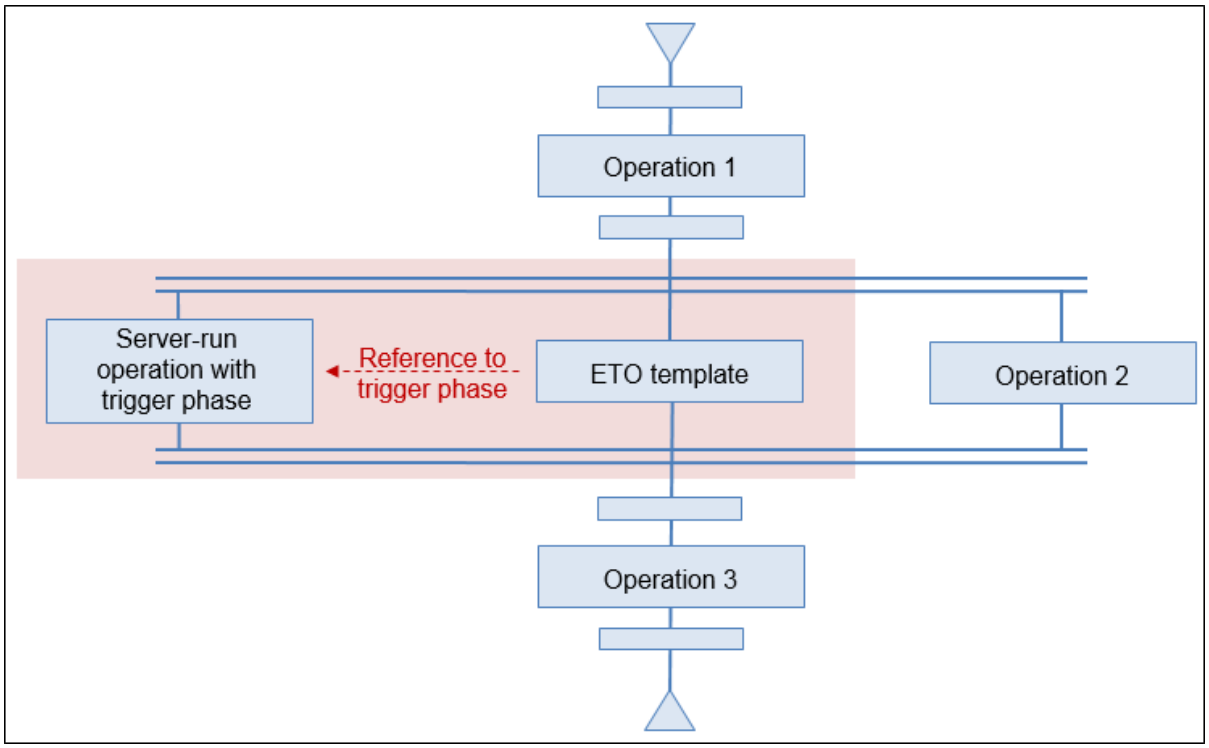


Figure 1: Event-triggered operation within a recipe

2.1 Trigger Phases

The following trigger phases are available:

- Time-based trigger (GID-2668001)
  The **Time-based trigger** phase allows to automatically create runs of an event-triggered operation (ETO) based on a time-related cycle. The time until the next run will be created is displayed on the ETO template in the Cockpit.
  The phase is designed for being run on a server without user interaction.
- Counter-based trigger (GID-2668002)
  The **Counter-based trigger** phase allows to automatically create runs of an event-triggered operation (ETO) based on a counter-based cycle.
  The phase is designed for being run on a server without user interaction.

The following rules apply with respect to start and completion of trigger processing of a trigger phase. For details, see **Business Logic (SR0400.2+)** of the Time-based trigger phase (GID-2668336)and **Business Logic (SR0405.2+)** of the Counter-base trigger phase (GID-2668341).

- A trigger phase becomes active automatically according to SFC, but trigger processing does not start until at least one related ETO template has become active. That means that the template is visible in the Cockpit of all running Production Execution Clients, according to their station-level dispatching.
- If none of the related ETO templates becomes active, the trigger phase is completed automatically after its timeout period has elapsed.
- If trigger processing has started due to active ETO templates, the trigger phase is completed automatically as soon as there is no related ETO template active anymore. That means that the active ETO templates have been removed from the Cockpit by the operator.
- In case a unit procedure is paused by the operator, also the trigger processing of the trigger phases is paused. When the pause period of the unit procedure is ended by the operator, the trigger processing continues based on a new re-calculated trigger schedule.

2.1.1 How to Model Recipes with ETOs and Trigger Phases

This section illustrates potential issues that may occur during recipe execution and how to avoid them during recipe design.

2.1.1.1 Issue 1: Trigger Phase Is Activated with Delay

The delayed activation of a trigger phase is probably caused by the position of **Operation 2** within the trigger/ETO-related parallel branch.

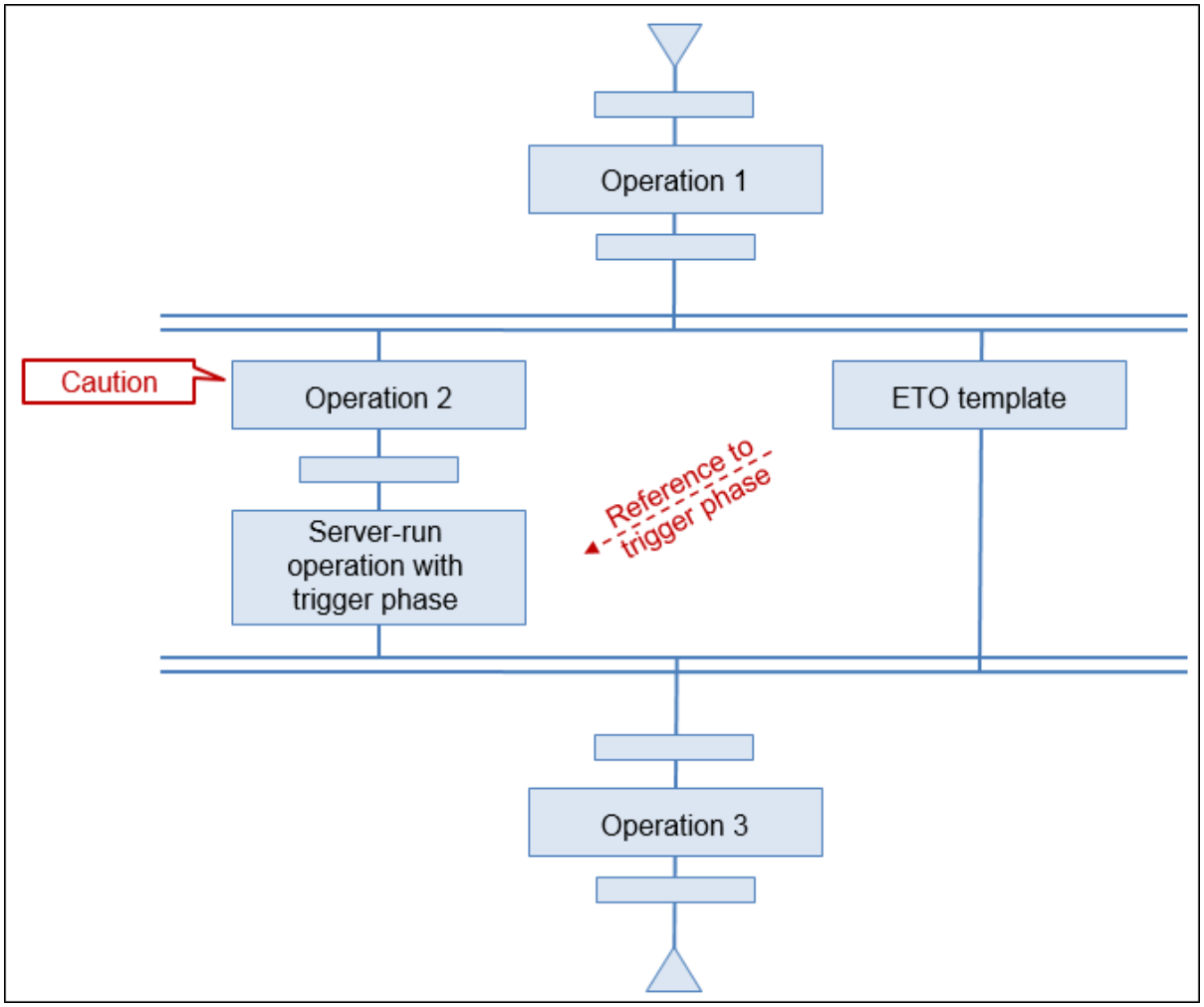


Figure 2: Issue 1: Trigger phase is activated with delay

The recipe design results in the following system behavior:

- The **ETO template** already becomes visible within the Cockpit, while automatic trigger processing is not started yet.
- The trigger phase and its trigger processing are not started unless **Operation 2** has been completed.

2.1.1.2 Issue 2: ETO Template Is Activated with Delay

The delayed activation of an ETO template is probably caused by the position of **Operation 2** within the trigger/ETO-related parallel branch.

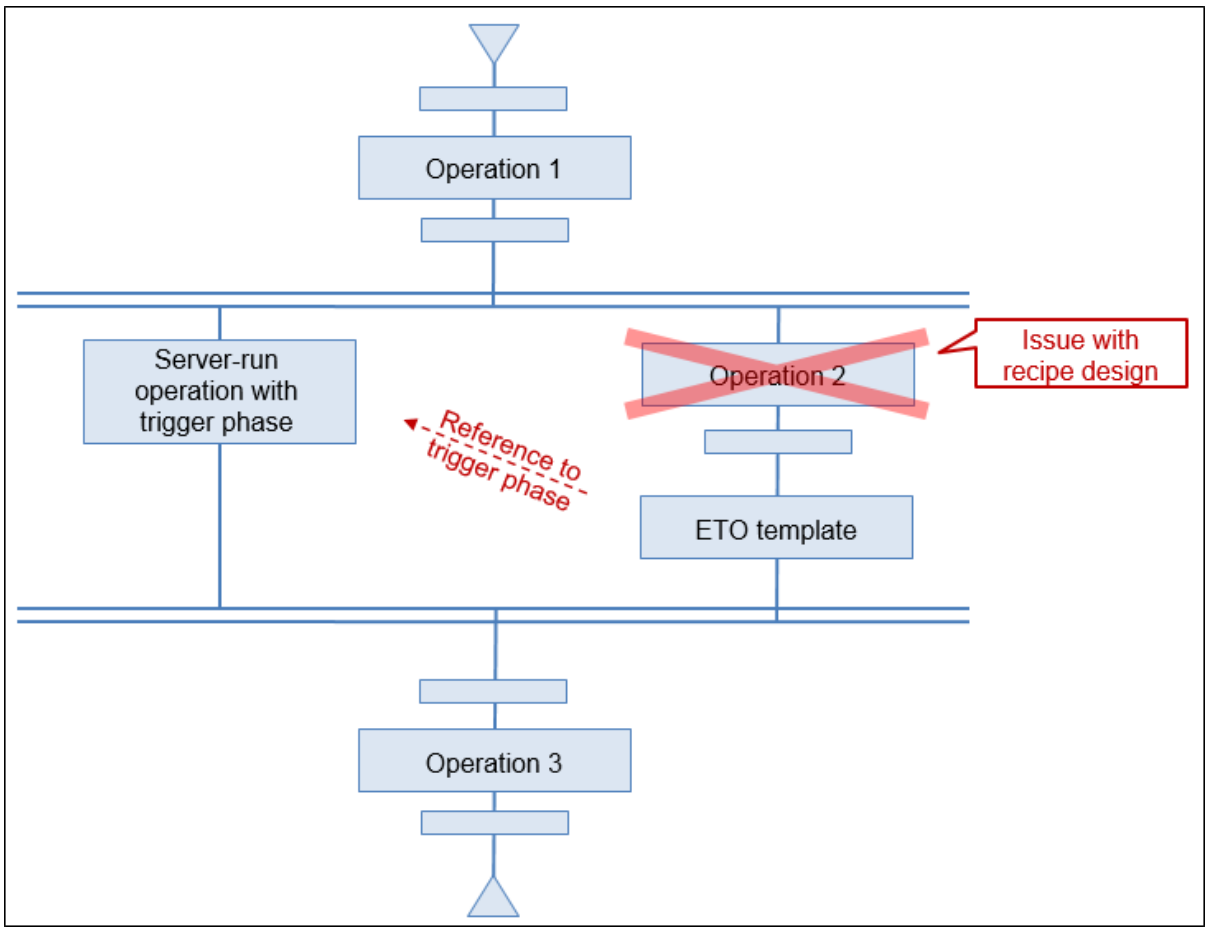


Figure 3: ETO template is activated with delay

The recipe design results in the following system behavior:

- The trigger phase becomes active, but trigger processing does not start unless **Operation 2** has been completed and **ETO template** has been activated.
- Trigger processing only waits for the **ETO template** to be activated within its defined timeout period.
- After the timeout period has elapsed, the trigger phase is completed automatically.
- If the **ETO template** becomes active after the trigger phase has been completed, automatic trigger events are not available for creation of new runs of the **ETO template**.

2.1.1.3 Solution for Issue 1, 2: Start ETOs Simultaneously

Placing **Operation 2** before the trigger/ETO-related parallel branch makes sure that the trigger phase and the **ETO template** are activated simultaneously and trigger processing can start as expected, per configuration of the trigger phase.

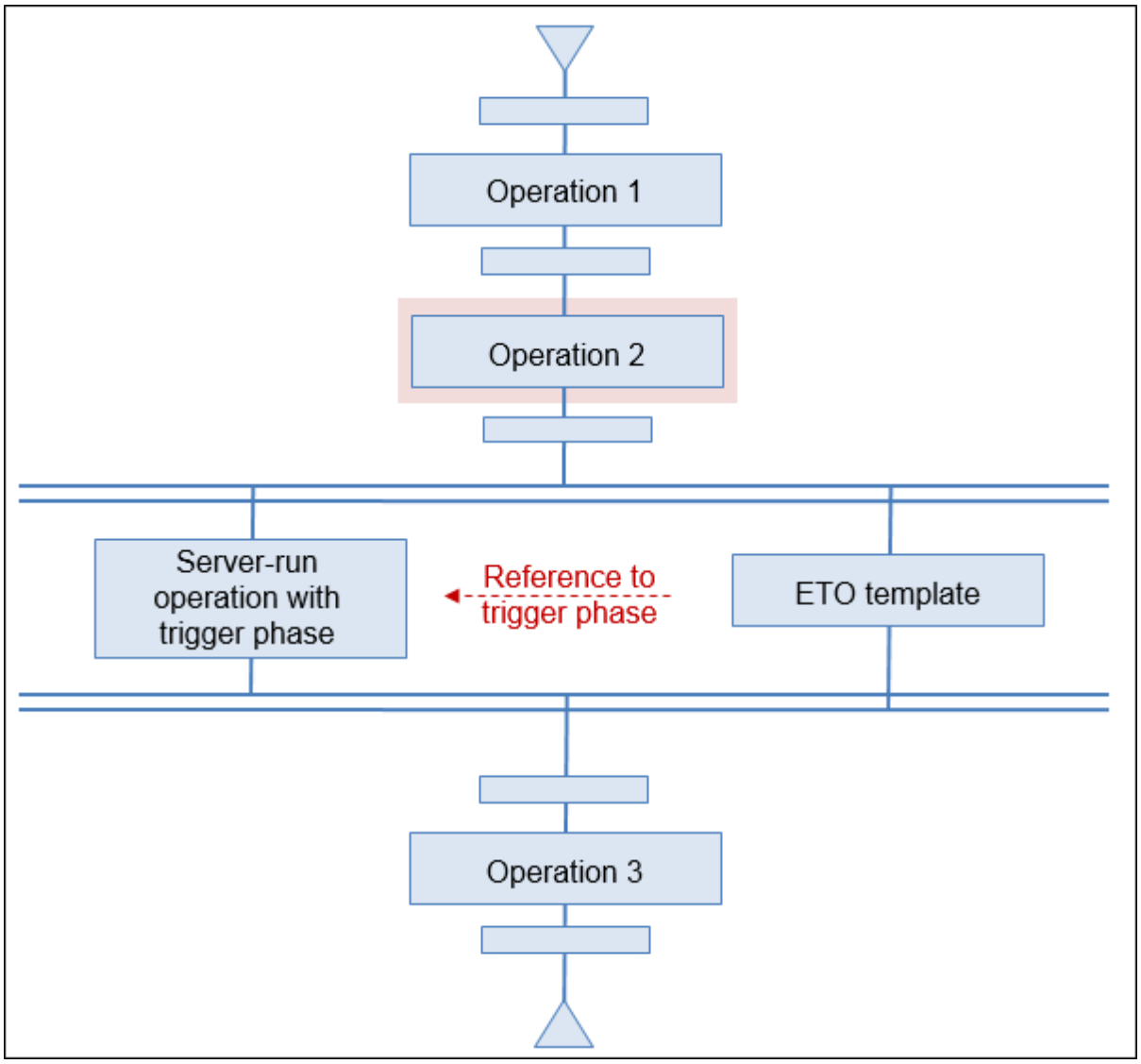


Figure 4: Solution for issue 1, 2: Start ETOs simultaneously

2.1.1.4 Issue 3: Subsequent ETO Templates Reference the Same Trigger Phase

Subsequent ETO templates must not reference the same trigger phase, assuming that both **ETO templates** should be triggered automatically by the phase.

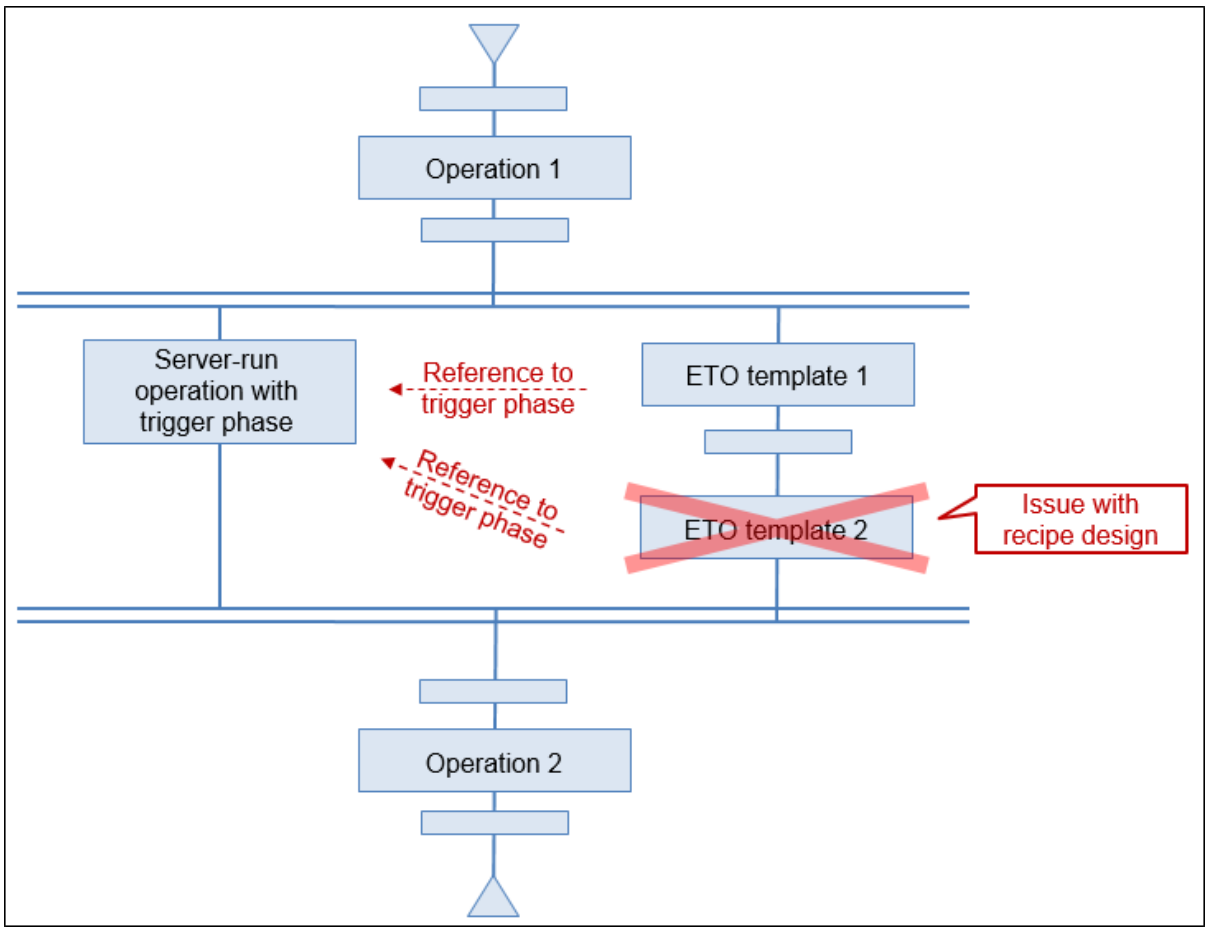


Figure 5: Issue 3: Subsequent ETO templates reference the same trigger phase

The recipe design results in the following system behavior:

- Trigger processing is completed automatically once no ETO template is active anymore. In this specific scenario, this is usually the case after **ETO template 1** is completed.
- As a consequence, when **ETO template 2** becomes active, automatic trigger events are no longer available for creating new runs of **ETO template 2**.

2.1.1.5 Solution for Issue 3: Provide Sequential Trigger Phases for Sequential ETO Templates

Place two sequential trigger phases into the server-run operation. This results in the following system behavior:

- **Phase 1** is completed automatically along with the completion of the **ETO template 1**.
- **Phase 1** is ready for trigger processing of **ETO template 2**.

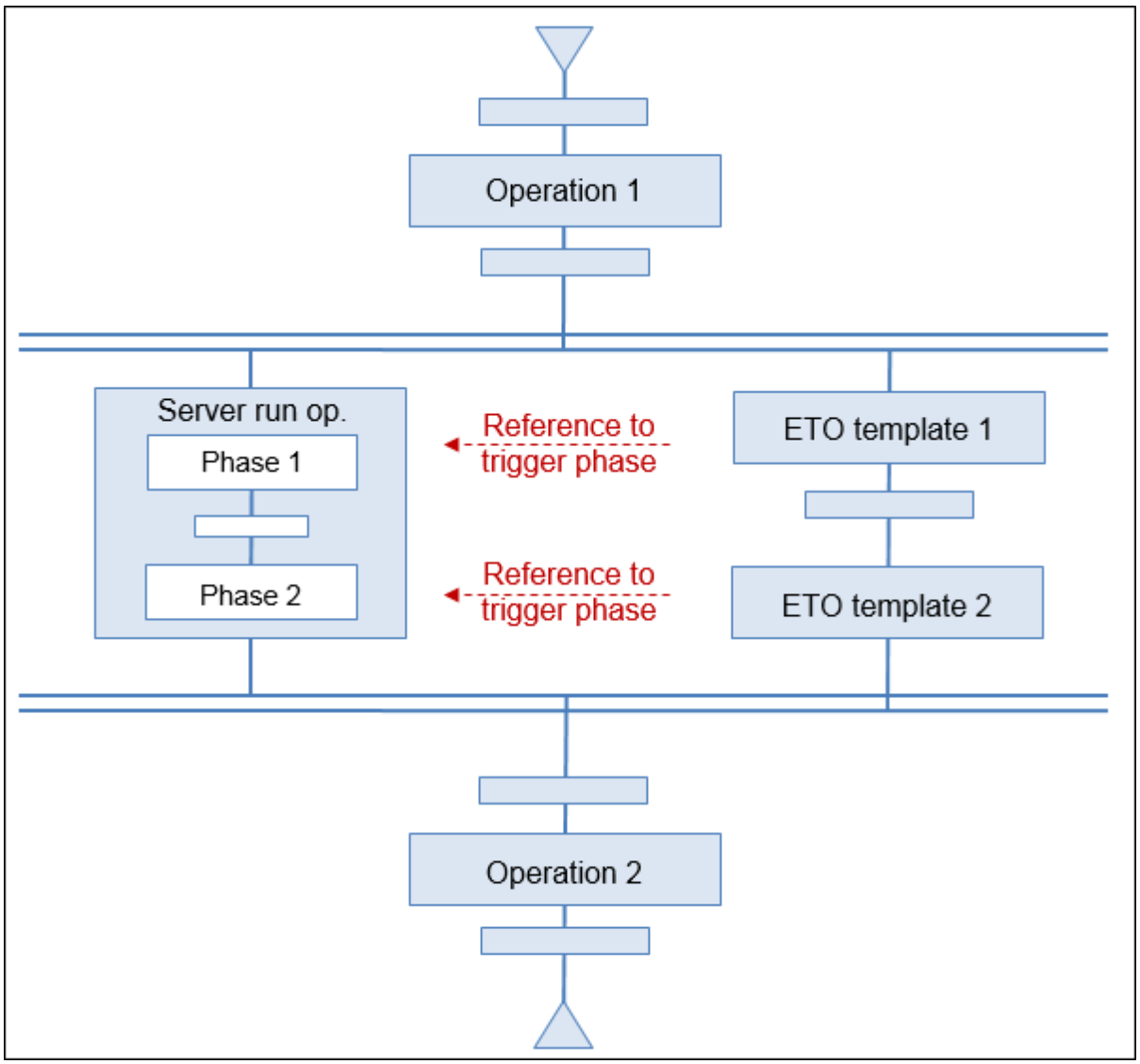


Figure 6: Solution for issue 3: Provide sequential trigger phases for sequential ETO templates

2.1.1.6 Issue 4: Loop within a Trigger/ETO-related Parallel Branch

Loops that include an ETO template must not be designed within a trigger/ETO-related parallel branch.

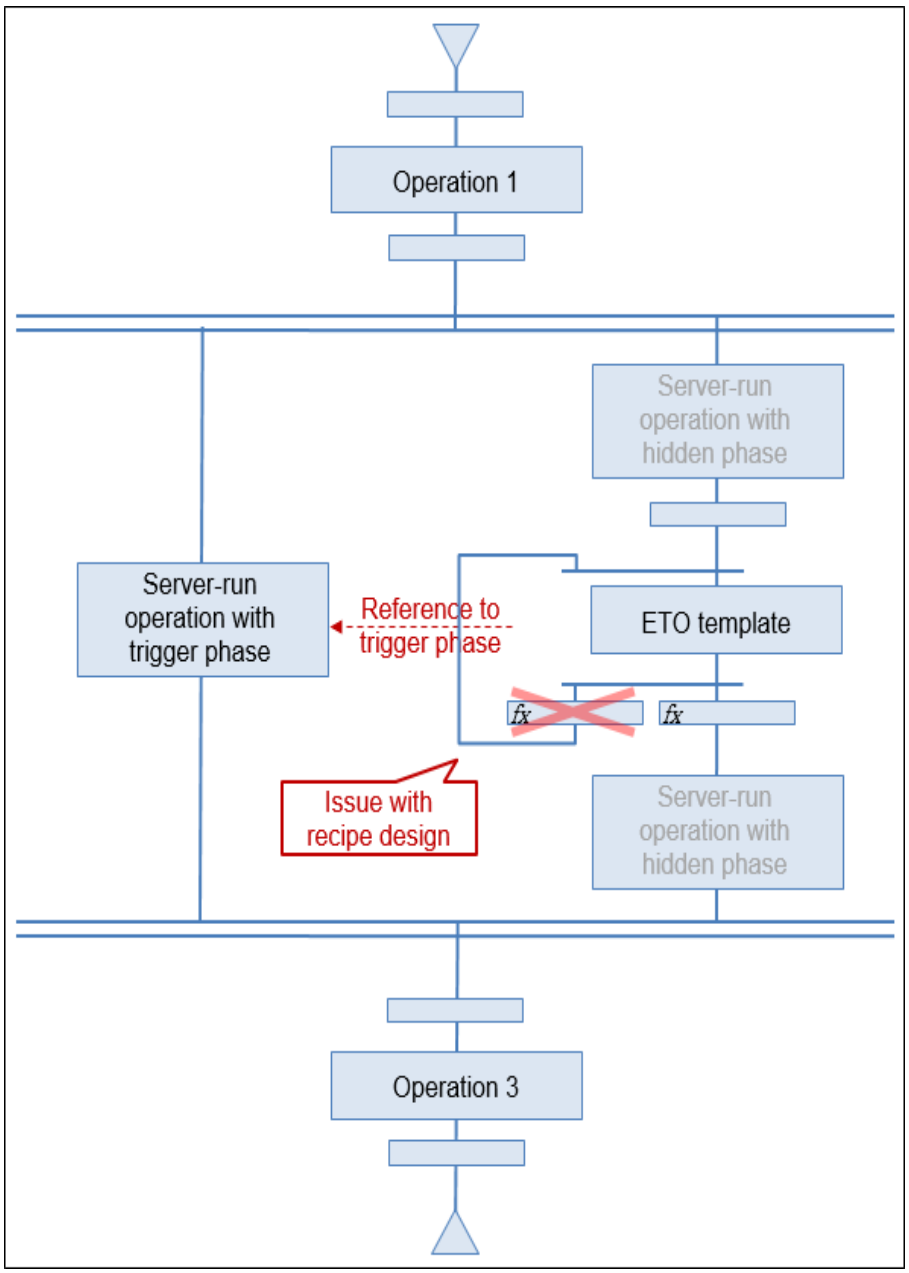


Figure 7: Issue 4: Loop within a trigger/ETO-related parallel branch

The recipe design results in the following system behavior:

- Trigger processing is completed automatically once no ETO template is active anymore, which means after the **ETO template** has been completed for the first time.
- As a consequence, when the **ETO template** is looped and becomes active again, automatic trigger events are no longer available for creating new runs of the ETO template.

2.1.1.7 Solution for Issue 4: Loop includes the Trigger/ETO-related Parallel Branch

Loops, if required, always need to enclose the entire trigger/ETO-related parallel branch.

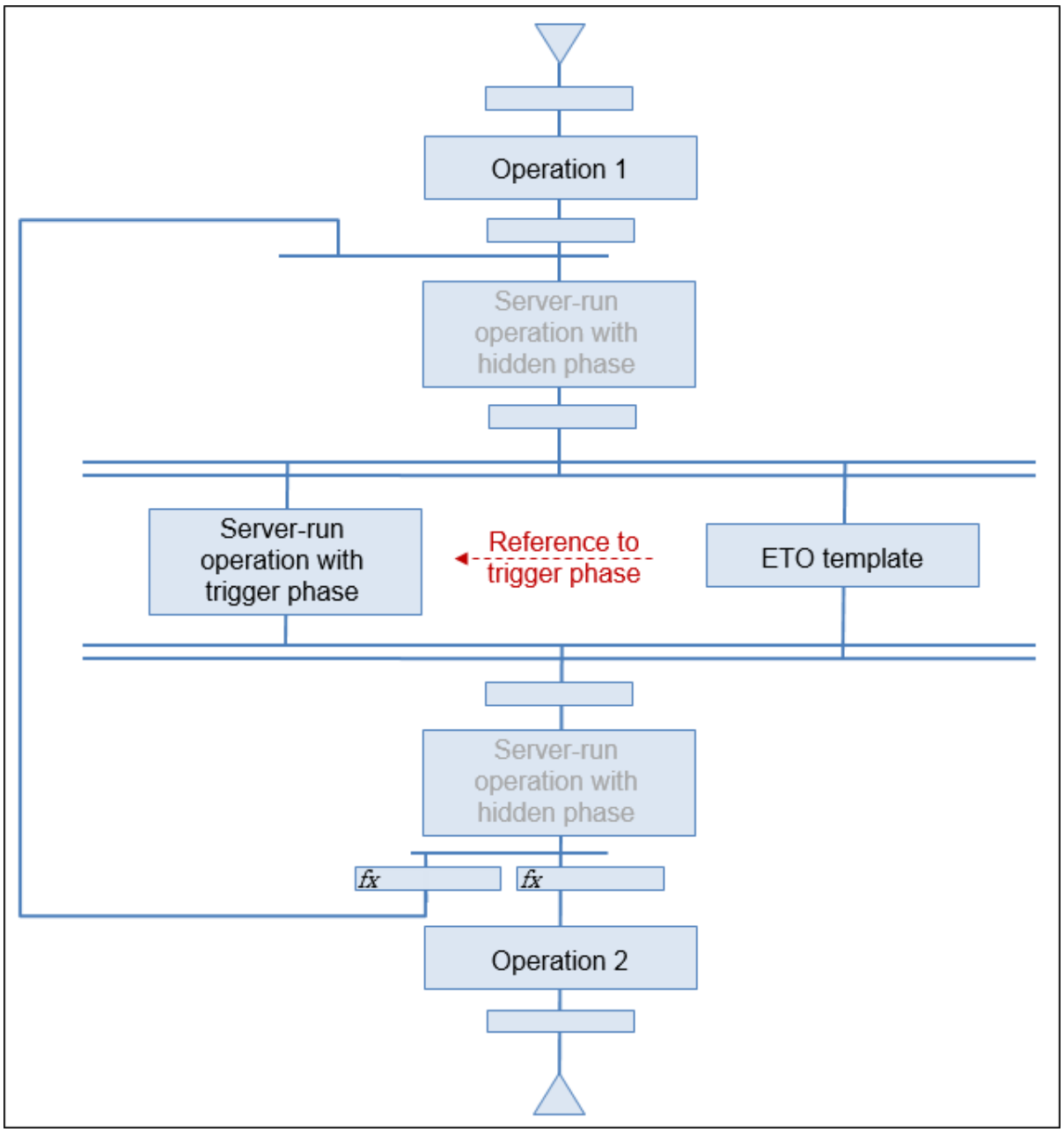


Figure 8: Solution for issue 4: Loop includes the trigger/ETO-related parallel branch

2.2 Data Collection and Data Representation Phases

The following data collection and data representation phases are available:

- Get values (GID-2668003)
  The **Get values** phase allows an operator to collect up to ten values of the following data types: Boolean Value, Measured Value, Option Value, String Value, and Timestamp Value.
- Show values (GID-2668004)
  The **Show values** phase allows an operator to view the data that has been collected along with the **Get values** phase (GID-2668003)across multiple runs, which are based on loops or ETO templates. The data is represented in a table format and supports up to two table sets with up to five columns with values of the following data types: Boolean Value, Measured Value, Option Value, String Value, and Timestamp Value.

2.2.1 Combination of the Data Collection and Data Representation Phases

During recipe design, the following rules apply with respect to the combination of **Get values** and **Show values** phases:

- A **Show values** phase always needs to reference a **Get values** phase.
- Both phases must use the same bundle identifiers during configuration.
- A **Show values** phase can be placed within or outside the operation that contains its referenced **Get values** phase.

2.2.2 Scope of Data Collection

The **Show values** phase provides two different modes related to the scope of the data collection**.**

- Data collection **across** operation runs (default):
  Data is collected across all runs of an operation and their phase instances, even across multiple unit procedures if a unit procedure was reactivated.

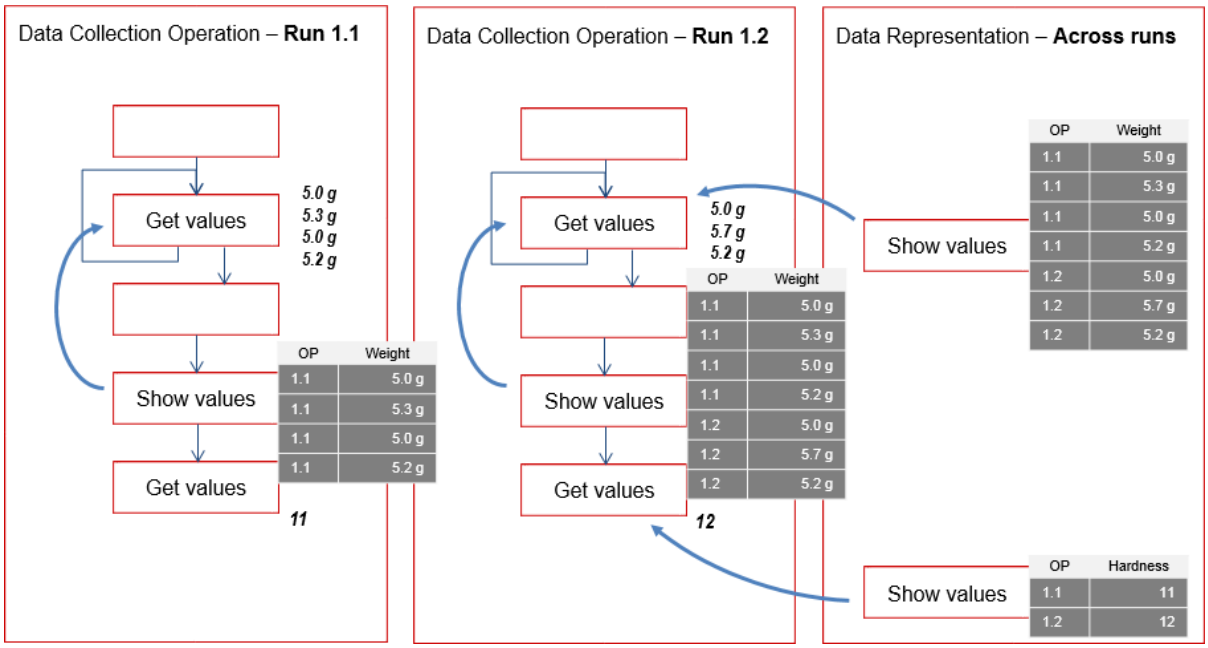


Figure 9: Data collection across operation runs

- Data collection **within** an operation run:
  Data is collected only from the phase instances within the given operation.

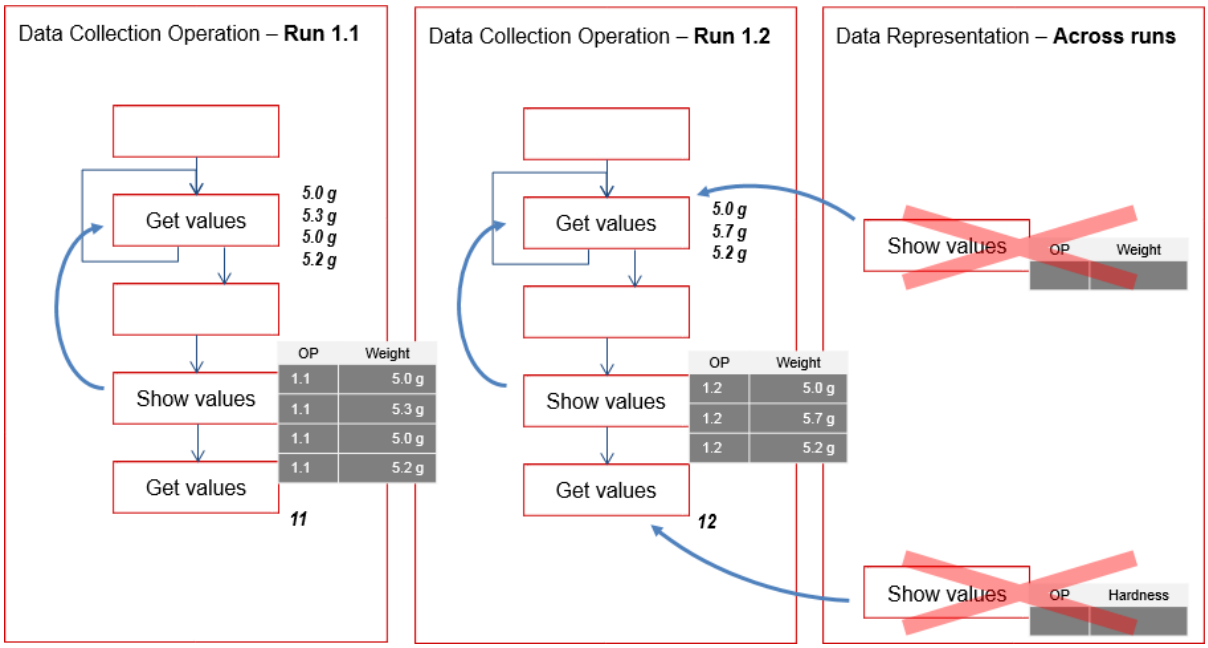


Figure 10: Data collection across operation runs

3 Time-based Trigger Phase (SR0400+)

The **Time-based trigger** phase allows to automatically create runs of an event-triggered operation (ETO) based on a time-related cycle. The time until the next run will be created is displayed on the ETO template in the Cockpit.

Example use cases are:

- In manufacturing, average tablet weight and hardness have to be recorded every 30 minutes.
- In packaging, visual checks of filled folding cartons have to be executed every hour.

The number of fired triggers and their time information is stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report (GID-2671569).

Anomalies that occur during processing are covered by the phase exception handling (GID-2668338)(e.g. timeout of the phase).

The information about the time until the next run of an ETO will be triggered is provided in order to display it on the ETO template in the Cockpit.

3.1 Layout

The phase provides a layout for its representation in the sub-report (GID-2671569).

3.1.1 Representation during Execution

As a server-run phase, the phase has no graphical representation (UI).

3.1.2 Representation in Navigator

As a server-run phase, the phase is not visible in the Navigator.

3.1.3 Representation in Sub-report (SR0400.5+)

The sub-report contains the following information:

3.1.3.1 Common sub-report elements (Framework capability)

- <Start time>
- <Completion time>
- <Unit procedure> / <operation> / <phase>
- <Work center> / <station> / <device> - <phase completion user>

For phases running on a server, the phase completion-user corresponds to the system.

3.1.3.2 GID-2671568 SUB-REPORT ELEMENTS (SR0400.5.1)

- Delay time, cycle time
- Timeout
- Number of fired triggers
- List of pause events: Paused from <timestamp> until <timestamp>

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.1.4 Representation in Sub-record

The sub-record contains the following information:

3.1.4.1 GID-2671569 BATCH RECORD-RELATED ELEMENTS (SR0400.5.2)

Timestamp information of fired triggers

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.2 Business Logic (SR0400.2+)

The phase implements the following business logic.

3.2.1 GID-2669699 Phase activation (SR0400.2.1)

- Function: Start the trigger processing
- Trigger: Phase becomes active
- Postcondition: Trigger processing is started

Step	#	Description
Phase activation	10	Phase checks ▪ if the unit procedure is currently paused (check passes if the unit procedure is not paused), ▪ if at least one of the relevant ETO templates is already active (check passes if at least one ETO template is active), and ▪ if the timeout period has not elapsed yet (defined with the **Timeout period (SR0400.8.3)** process parameter (GID-2671572)) (check passes if an ETO template has become active before the timeout period has elapsed). If all checks have passed, continue with step 10.4.
	10.1	If the unit procedure is paused, the phase waits without any action (no trigger processing, no timeout clock is running) until the unit procedure is continued.
	10.2	If the unit procedure is running, no relevant ETO template is active, and the timeout period has not elapsed, trigger processing is still waiting and timeout clock is running.
	10.3	If the timeout period has elapsed without any ETO becoming active, the phase is completed automatically according to the **Phase completion (SR0400.2.5)** function (GID-2669703).
	10.4	If a relevant ETO template becomes active, trigger processing starts according to the **Fire triggers (SR0400.2.2)** function (GID-2669700). At this point, the timeout period no longer applies.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.2.2 GID-2669700 Fire triggers (SR0400.2.2)

- Function: Fire the triggers
- Trigger: Trigger processing has started
- Postcondition: Triggers are fired

Step	#	Description
	5	If there is a delay time defined, the phase informs all ETO templates referencing the phase about the delay time until the first trigger will be fired.

Step	#	Description
Start trigger processing	10	Phase fires the first trigger after the delay time has elapsed (defined with the **Delay time (SR0400.8.1)** process parameter (GID-2671570)).
Delay time has elapsed	20	Phase repeatedly fires a trigger, each time the cycle time has elapsed (defined with the **Cycle time (SR0400.8.2)** process parameter (GID-2671571)and informs all ETO templates referencing the phase about the time until the next trigger will be fired.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.2.3 GID-2669701 Pause trigger processing (SR0400.2.3)

- Function: Pause/continue the trigger processing
- Precondition: Trigger processing is active
- Trigger: Unit procedure is paused/continued by the operator (for details, see **Pausing a Unit Procedure (SR1089.8.3)** in "Functional Requirement Specification Execution Framework" [A1] (GID-2668005))
- Postcondition: Trigger processing is paused/continued

Step	#	Description
Operator pauses unit procedure	10	At the very moment when the unit procedure of the phase is paused, trigger processing stops. No further triggers are fired automatically.
Operator continues paused unit procedure	20.1	At the very moment when the paused unit procedure of the phase is continued, trigger processing continues where it was stopped and continues to fire triggers according to the **Fire triggers (SR0400.2.2)** function (GID-2669700)and a new re-calculated trigger schedule. The new trigger schedule is based on the fact that the duration of the pause shall not count against the cycle time.
	20.2	In case no relevant ETO template was active during the pause period and the timeout period has not elapsed yet: trigger processing is still waiting and the timeout clock is running, however, the timeout clock is reset upon resume of the pause.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.2.4 GID-2669702 Resume trigger processing (SR0400.2.4)

- Function: Resume the trigger processing
  (for the continuation of a paused unit procedure, see **Pause trigger processing (SR0400.2.3)** function (GID-2669701))
- Precondition: Trigger processing is active
- Trigger: Phase is restarted, e.g. along with the restart of the operation that runs on the OES (for details, see **Resuming Server-run Operations (SR1200.1.3)** in "Functional Requirement Specification Execution Framework" [A1] (GID-2668005))
- Postcondition: Trigger processing resumes where it was interrupted

Step	#	Description
Phase is restarted	10	As soon as the phase is restarted, it checks if a trigger was missed.
	10.1	If no trigger was missed, the phase resumes the trigger processing based on the assumption that the cycle time clock has never stopped running. This means, the triggers continues to fire triggers according to the **Fire triggers (SR0400.2.2)** function (GID-2669700)and according to its original trigger schedule.
	10.2	If triggers were missed during the time the phase was not running, they are considered to be lost and will not be re-fired when the trigger processing is resumed. The phase fires a trigger and informs about the time until the next trigger will be fired as soon as reasonable, ▪ if the unit procedure is not paused, immediately, ▪ if the unit procedure is paused, as soon as it is continued, and continues to fire the subsequent triggers according to the **Fire triggers (SR0400.2.2)** function (GID-2669700)and a re-calculated trigger schedule.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.2.5 GID-2669703 Phase completion (SR0400.2.5)

- Function: Completion of phase
- Trigger: Timeout period has elapsed or no ETO template is active anymore
- Postcondition: Phase is completed

Step	#	Description
Timeout period has elapsed	10	If the timeout period has elapsed, the phase is completed automatically without having fired any triggers and creates a **Timeout (SR0400.3.2.1)** system-triggered exception (GID-2669701).
None of the previously running related ETO templates is active any more	20	Phase stops trigger processing and is completed automatically.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3 Process Parameters (SR0400.8+)

The following process parameters define the behavior of the phase.

3.3.1 Basic Parameters

3.3.1.1 GID-2671570 Delay time (SR0400.8.1)

Attribute	Type	Comment
Duration	Duration	Defines the delay between phase start and its first trigger. Null is interpreted as 0 seconds during execution.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.1.2 GID-2671571 CYCLE TIME (SR0400.8.2)

Attribute	Type	Comment
Duration	Duration	Defines the duration between two consecutive triggers. Minimum default cycle time is 30 seconds, i.e. null or a duration less than 30 seconds is interpreted as 30 seconds during execution.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.1.3 GID-2671572 TIMEOUT PERIOD (SR0400.8.3)

Attribute	Type	Comment
Duration	Duration	Defines the duration that the phase waits for its event-triggered operation to become active, before the phase is automatically completed. Null is interpreted as 30 minutes (default timeout) during execution.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.2 Configuration of System-triggered Exceptions

3.3.2.1 GID-2671573 TIMEOUT EXCEPTION (SR0400.8.4)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception. Since there is no operator interaction for the exception, it is not linked to a signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.

Attribute	Type	Comment
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Timeout (SR0400.3.2.1)** system-triggered exception (GID-2671574).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.4 Exceptions (SR0400.3+)

The phase supports system-triggered exceptions (GID-2668338)and their configuration by means of process parameters.

3.4.1 System-triggered Exceptions (SR0400.3.2+)

A system-triggered exception of a server-run phase is automatically recorded in the batch report without any user interaction.

The following system-triggered exceptions are available.

3.4.1.1 GID-2671574 Timeout (SR0400.3.2.1)

In case the timeout period has elapsed, the system automatically records a system-triggered exception:

Representation of the exception:

- <Exception text>
  (taken from **Timeout exception (SR0400.8.4)** process parameter (GID-2671573))
  Phase finished automatically due to timeout after <timeout period>.
- Example:
  Timeout occurred.
  Phase finished automatically due to timeout after 30 minutes.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

3.4.1.2 GID-2671575 TIMEOUT - LOGIC (SR0400.3.2.1.1)

- Trigger: Phase is completed automatically due to timeout
- Postcondition: Exception is recorded

Step	#	Description
Timeout occurs	10	Phase automatically records exception without user interaction.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

3.5 Output Variables

The following output variables are available to reference the phase's output.

3.5.1 Instance count (Framework capability)

- Data type: Long
- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.
  The count variable of a phase that has not been executed provides 0 as output value.

3.5.2 Start time (Framework capability)

- Data type: Timestamp
- Usage: The output variable provides the start time of the phase.

3.5.3 Completion time (Framework capability)

- Data type: Timestamp
- Usage: The output variable provides the completion time of the phase.

3.5.4 Identifier (Framework capability)

- Data type: String
- Usage: The output variable provides the identifier of the phase.

4 Counter-based Trigger Phase (SR0405+)

The **Counter-based trigger** phase allows to automatically create runs of an event-triggered operation (ETO) based on a counter-based cycle.

Example use cases are:

- In manufacturing, average tablet weight and hardness have to be recorded every 5,000 tablets.
- In packaging, visual checks of filled folding cartons have to be executed every 200 cartons.

The number of fired triggers and their count and timestamp information is stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report (GID-2669713).

Anomalies that occur during processing are covered by the phase exception handling (GID-2668338)(e.g. timeout of the phase).

4.1 Layout

The phase provides a layout for its representation in the sub-report (GID-2669713).

4.1.1 Representation during Execution

As a server-run phase, the phase has no graphical representation (UI).

4.1.2 Representation in Navigator

As a server-run phase, the phase is not visible in the Navigator.

4.1.3 Representation in Sub-report (SR0405.5+)

The sub-report contains the following information:

4.1.3.1 Common sub-report elements (Framework capability)

- <Start time>
- <Completion time>
- <Unit procedure> / <operation> / <phase>
- <Work center> / <station> / <device> - <phase completion user>

For phases running on a server, the phase completion-user corresponds to the system.

4.1.3.2 GID-2671577 SUB-REPORT ELEMENTS (SR0405.5.1)

- Delay count, cycle count
- Timeout
- Reading cycle
- Number of fired triggers
- List of pause events: Paused from <timestamp> until <timestamp>

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.1.4 Representation in Sub-record

The sub-record contains the following information:

4.1.4.1 GID-2671578 BATCH RECORD-RELATED ELEMENTS (SR0405.5.2)

- Count and timestamp information of fired triggers

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.2 Business Logic (SR0405.2+)

The phase implements the following business logic.

4.2.1 GID-2669715 Phase activation (SR0405.2.1)

- Function: Start the trigger processing
- Trigger: Phase becomes active
- Postcondition: Trigger processing is started

Step	#	Description
Phase activation	10	Phase checks ▪ if the unit procedure is currently paused (check passes if the unit procedure is not paused), ▪ if at least one of the relevant ETO templates is already active (check passes if at least one ETO template is active), and ▪ if the timeout period has not elapsed yet (defined with the **Timeout period (SR0405.8.3)** process parameter (GID-2671583)) (check passes if an ETO template has become active before the timeout period has elapsed). If all checks have passed, continue with step 10.4.
	10.1	If the unit procedure is paused, the phase waits without any action (no trigger processing, no timeout clock is running) until the unit procedure is continued.
	10.2	If the unit procedure is running, no relevant ETO template is active, and the timeout period has not elapsed, trigger processing is still waiting and timeout clock is running.
	10.3	If the timeout period has elapsed without any ETO template becoming active, phase is completed automatically according to the **Phase completion (SR0405.2.5)** function (GID-2669719).
	10.4	If a relevant ETO template becomes active, trigger processing starts according to the **Fire triggers (SR0405.2.2)** function (GID-2669716). At this point, the timeout period no longer applies.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.2.2 GID-2669716 Fire triggers (SR0405.2.2)

- Function: Fire the triggers
- Trigger: Trigger processing has started
- Postcondition: Triggers are fired

Step	#	Description
Start trigger processing	10	Phase reads the current count as a reference point and starts to repeatedly pull for the next counter reading according to the interval defined with the **Duration** attribute of the **Reading cycle (SR0405.8.9)** process parameter (GID-2671584).
	20	Phase fires the first trigger after the delay count has elapsed (defined with the **Delay count** attribute of the **Interval definition (SR0405.8.1)** process parameter (GID-2671582)).
After delay count has elapsed	30	Phase repeatedly fires a trigger, each time the cycle count has elapsed (defined with the **Cycle count** attribute of the **Interval definition (SR0405.8.1)** process parameter (GID-2671582)).

Technical description:

- **currentCounter** value is read from the automation layer and compared to the **scheduledCounter** value.
- If **currentCounter value >= scheduledCounter value**, a trigger is fired.
- Initial setting: **scheduledCounter value = NULL**
- As soon as trigger processing is started:
  scheduledCounter(new) value = currentCounter value + delayCount
- As soon as first trigger is fired (after delay count):
  scheduledCounter(new) value = scheduledCounter(old) value + cycleCount

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.2.3 GID-2669717 Pause trigger processing (SR0405.2.3)

- Function: Pause/continue the trigger processing
- Precondition: Trigger processing is active
- Trigger: Unit procedure is paused/continued by the operator (for details, see **Pausing a Unit Procedure (SR1089.8.3)** in "Functional Requirement Specification Execution Framework" [A1] (GID-2668005))
- Postcondition: Trigger processing is paused/continued

Step	#	Description
Operator pauses unit procedure	10	At the very moment when the unit procedure of the phase is paused, the phase reads the current count as a "Pause started" reference point and trigger processing stops. No further triggers are fired automatically.
Operator continues paused unit procedure	20	At the very moment when the paused unit procedure of the phase is continued, trigger processing continues where it was stopped. This means, the phase reads the current count as a "Pause finished" reference point and continues to fire triggers according to the **Fire triggers (SR0405.2.2)** function (GID-2669716)and a new re-calculated trigger schedule. The new trigger schedule is based on the fact that any increase of the count that may have occurred between "Pause started" and "Pause finished" shall be ignored. In case the system detects a reset of the counter value, phase creates a **Counter reset (SR0405.3.2.3)** system-triggered exception (GID-2669717)and re-calculates the trigger schedule according to the exception.
	20.1	In case either the "Pause started" or the "Pause finished" count cannot be read, phase continues / resumes the trigger processing based on the assumption that the unit procedure has not been paused at all. This means, the phase continues to fire triggers according to the **Fire triggers (SR0405.2.2)** function (GID-2669716)and according to its original trigger schedule. With respect to the count that could not be read, the phase creates an **Automation error (SR0405.3.2.2)** system-triggered exception (GID-2671590). As soon as the automation interface (AI) becomes available again, phase reads the current count and checks if a trigger was missed according to the **Resume trigger processing (SR0405.2.4)** function (GID-2669718). The system adds a comment to the already recorded exception according to the **Automation error - Resume (SR0405.3.2.2.2)** function (GID-2671592)of the **Automation error (SR0405.3.2.2)** system-triggered exception (GID-2671590)
	20.2	In case no relevant ETO template was active during the pause period and the timeout period has not elapsed yet: trigger processing is still waiting and the timeout clock is running, however, the timeout clock is reset upon resume of the pause.

The pause-related system behavior is based on the assumption that, along with pausing a unit procedure by the operator, typically also the counter on automation level is paused.
However, it also covers use cases where, e.g. IPC needs to be paused due to problems with the quality of the produced boxes. So, while the unit procedure is paused in MES, you continue to run the machine to adjust the parameters, until produced boxes are back in spec. At the same time, the counter value has been increased, but the counts were all related to the adjustment of the parameters, i.e. to waste.
If the paused unit procedure now is continued by the operator, all the waste-related counts that occurred during the pause-related time window are ignored and a new trigger schedule is re-calculated by the system accordingly.

Technical description

- "Pause started" is reflected by the **pauseStartCounter** value.
- "Pause finished" is reflected by the **pauseAfterCounter** value.
- When UP is paused,
  pauseStartCounter value = currentCounter value
- When UP is continued,
  pauseAfterCounter value = currentCounter value and
  scheduledCounter(new) value = scheduledCounter(old) value + pauseAfterCounter - pauseStartCounter
- If counter reset is detected (**currentCounter value < lastGoodCounter value**):
  When UP is paused,
  pauseStartCounter value = lastGoodCounter value and
  scheduledCounter(new) value = lastGoodCounter value
  When UP is continued, trigger is fired and
  scheduledCounter(new) value = currentCounter value + cycle count
- If an AI exception occurred related to "Pause started" or "Pause finished":
  When UP is continued, the pause basically is ignored and **scheduledCounter(new)** value is set dependent on if a trigger was missed.
  No trigger missed: **scheduledCounter(new)** is not updated.
  Trigger missed: Trigger is fired and
  scheduledCounter(new) value = currentCounter value + cycle count

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.2.4 GID-2669718 Resume trigger processing (SR0405.2.4)

- Function: Resume the trigger processing
  (for the continuation of a paused unit procedure, see **Pause trigger processing (SR0405.2.3)** function (GID-2669717))
- Precondition: Trigger processing is active

- Trigger: Phase is restarted, e.g. along with the restart of the operation that runs on the OES (for details, see **Resuming Server-run Operations (SR1200.1.3)** in "Functional Requirement Specification Execution Framework" [A1] (GID-2668005)) or automation interface (AI) becomes available again
- Postcondition: Trigger processing resumes where it was interrupted

Step	#	Description
Phase is restarted or automation interface (AI) becomes available again	10	As soon as the phase is restarted or the AI becomes available again, it reads the current count and checks if a trigger was missed. In case the system detects a reset of the counter value, phase creates a **Counter reset (SR0405.3.2.3)** system-triggered exception (GID-2671593)and re-calculates the trigger schedule according to the exception.
	10.1	If no trigger was missed, phase resumes the trigger processing based on the assumption that the cycle counter intervals have never stopped running. This means, the phase continues to fire triggers according to the **Fire triggers (SR0405.2.2)** function (GID-2669716)and according to its original trigger schedule.
	10.2	If triggers were missed during the time the phase was not running or the AI was not available, they are considered to be lost and will not be re-fired when the trigger processing is resumed. The phase fires a trigger as soon as reasonable, ▪ if the unit procedure is not paused and the AI is available, immediately, ▪ if the unit procedure is paused or the AI is not available, as soon as the unit procedure is continued and the AI is available again, and continues to fire the subsequent triggers according to the **Fire triggers (SR0405.2.2)** function (GID-2669716)and a re-calculated trigger schedule.

The resume-related system behavior is based on the assumption that the system does not know what kind of error happened (e.g. Was the machine down as well or did the machine continue to run and produce boxes while only the counter signal was down?). So, just to be on the safe side, as soon as the counter signal is back, the system checks if a trigger was missed.
Only if the system can determine that no trigger was missed, will it continue to fire triggers according to its original trigger schedule.
In all other cases (trigger was missed or no way to determine if a trigger was missed), the system fires a new trigger. This trigger now is used as the starting point to re-calculate a new trigger schedule, based on the original and still valid cycle count interval between two consecutive triggers.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.2.5 GID-2669719 Phase completion (SR0405.2.5)

- Function: Completion of phase
- Trigger: Timeout period has elapsed or no ETO template is active anymore
- Postcondition: Phase is completed

Step	#	Description
Timeout period has elapsed	10	If the timeout period has elapsed, the phase is completed automatically without having fired any triggers and creates a **Timeout (SR0405.3.2.1)** system-triggered exception (GID-2671588).
None of the previously running related ETO templates is active any more	20	Phase stops trigger processing and is completed automatically.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3 Process Parameters (SR0405.8+)

The following process parameters define the behavior of the phase.

4.3.1 Reference Parameters

4.3.1.1 GID-2671579 Identified equipment entity (SR0405.8.5)

Attribute	Type	Comment
Equipment object	Reference	Reference to the output of a preceding phase that provides an identified equipment entity.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3.1.2 GID-2671580 NUMERIC PROPERTY (SR0405.8.6)

Attribute	Type	Comment
Property	String	Equipment property to be read.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3.1.3 GID-2671581 PROPERTY SELECTION EDITOR (SR0405.8.6.1)

The system provides a Property Selection editor for selecting an equipment property based on its data type (numeric, string, boolean). Here only properties of numeric data types are selectable.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3.2 Basic Parameters

4.3.2.1 GID-2671582 INTERVAL DEFINITION (SR0405.8.1)

Attribute	Type	Comment
Delay count	Long	Defines the number of counts between phase start and its first trigger. Null is interpreted as 0 during execution.
Cycle count	Long	Defines the interval between two consecutive triggers. Minimum default cycle count is 1, i.e. null or 0 is interpreted as 1 during execution.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3.2.2 GID-2671583 TIMEOUT PERIOD (SR0405.8.3)

Attribute	Type	Comment
Duration	Duration	Defines the duration that the phase waits for its event-triggered operation to become active, before the phase is automatically completed. Null is interpreted as 30 minutes (default timeout) during execution.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3.2.3 GID-2671584 READING CYCLE (SR0405.8.9)

Attribute	Type	Comment
Duration	Duration	Defines the interval in seconds between two consecutive reading actions. Null or any value less than 2 seconds is interpreted as 2 seconds during execution.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3.3 Configuration of System-triggered Exceptions

4.3.3.1 GID-2671585 TIMEOUT EXCEPTION (SR0405.8.4)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception. Since there is no operator interaction for the exception, it is not linked to a signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.

Attribute	Type	Comment
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Timeout (** (GID-2671588)**)** system-triggered exception link.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3.3.2 GID-2671586 AUTOMATION ERROR EXCEPTION (SR0405.8.7)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception. Since there is no operator interaction for the exception, it is not linked to a signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Automation error (SR0405.3.2.2)** system-triggered exception (GID-2671590).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3.3.3 GID-2671587 COUNTER RESET EXCEPTION (SR0405.8.8)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception. Since there is no operator interaction for the exception, it is not linked to a signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Counter reset (SR0405.3.2.3)** system-triggered exception (GID-2671593).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.4 Exceptions (SR0405.3+)

The phase supports system-triggered exceptions (GID-2669723)and their configuration by means of process parameters (GID-2668342).

4.4.1 System-triggered Exceptions (SR0405.3.2+)

A system-triggered exception of a server-run phase is automatically recorded in the batch report without any user interaction.

The following system-triggered exceptions are available.

4.4.1.1 GID-2671588 TIMEOUT (SR0405.3.2.1)

In case the timeout period has elapsed, the system automatically records a system-triggered exception:

Representation of the exception:

- <Exception text>
  (taken from **Timeout exception (SR0405.8.4)** process parameter (GID-2671585))
  Phase finished automatically due to timeout after <timeout period>.

- Example:
  Timeout occurred.
  Phase finished automatically due to timeout after 30 minutes.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.4.1.2 GID-2671589 Timeout - Logic (SR0405.3.2.1.1)

- Trigger: Phase is completed automatically due to timeout
- Postcondition: Exception is recorded

Step	#	Description
Timeout occurs	10	Phase automatically records exception without user interaction.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.4.1.3 GID-2671590 Automation error (SR0405.3.2.2)

In case the counter-related property cannot be read by the automation interface, the system automatically records a system-triggered exception.

Representation of the exception:

- <Exception text>
  (taken from **Automation error exception (SR0405.8.7)** process parameter (GID-2671586))
  Value of the <property identifier> property could not be read.
  System errors: <automation-related message>.
- Example:
  Blister machine-related automation error occurred.
  Value of the Counter property could not be read.
  System errors: <automation-related message>.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.4.1.4 GID-2671591 Automation error - Logic (SR0405.3.2.2.1)

- Trigger: Counter-related property cannot be read by the automation interface.
- Postcondition: Exception is recorded

Step	#	Description
Automation error occurred	10	Phase automatically records exception without user interaction.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.4.1.5 GID-2671592 AUTOMATION ERROR - RESUME (SR0405.3.2.2.2)

- Trigger: Counter-related property can be read by the automation interface.
- Postcondition: Comment is added to the corresponding exception

Step	#	Description
Automation error is resolved	10	As soon as the phase is able to read the counter-related property again, the system adds a comment to the exception (Access to the <property identifier> property has been reestablished.).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.4.1.6 GID-2671593 COUNTER RESET (SR0405.3.2.3)

In case the external counter is reset to a smaller value or a counter overflow occurs, the system automatically resets the actual count cycle interval and records a system-triggered exception.

Representation of the exception:

- <Exception text>
  (taken from **Counter reset exception (SR0405.8.8)** process parameter (GID-2671587))
  A reset of the external counter occurred and caused a reset of the count cycle interval.
- Example:
  Tableting machine-related counter issue.
  A reset of the external counter occurred and caused a reset of the count cycle interval.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.4.1.7 GID-2671594 COUNTER RESET- LOGIC (SR0405.3.2.3.1)

- Trigger: External counter is reset to a smaller value.
- Postcondition: Count cycle interval is reset and exception is recorded

Step	#	Description
External counter reset detected	10	Phase automatically records exception without user interaction.
	20	Phase fires a new trigger and resets the count cycle interval.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.5 Output Variables

The following output variables are available to reference the phase's output.

4.5.1 Instance count (Framework capability)

- Data type: Long
- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.
  The count variable of a phase that has not been executed provides 0 as output value.

4.5.2 Start time (Framework capability)

- Data type: Timestamp
- Usage: The output variable provides the start time of the phase.

4.5.3 Completion time (Framework capability)

- Data type: Timestamp
- Usage: The output variable provides the completion time of the phase.

4.5.4 Identifier (Framework capability)

- Data type: String
- Usage: The output variable provides the identifier of the phase.

5 Get Values Phase (SR0440+)

The **Get values** phase allows an operator to collect up to ten values of the following data types:

- Boolean Value: choice between Yes and No (true and false),
- Measured Value (measured value): value and unit of measure,
- Option Value (choice list): choice from a pre-defined list of options,
- String Value, and
- Timestamp Value: date and time.

Example use cases are:

- Recording of tablet weights during IPC
  The tablet weight must range between 5 g and 6 g. These boundary values can be defined as limits and corresponding limit violations can be tracked as exceptions.
- Recording of visual appearance during IPC
  During the inspection of a liquid product sample, the visual appearance of the sample can be selected from a pre-defined list (e.g., Transparent, Cloudy, Dark).
- Recording of the execution of mandatory checks during IPC
  The execution of a visual check needs to be recorded by confirming with **Yes**.
- Recording of used equipment that is not inventoried by PharmaSuite.
- Recording of the execution time when a bin is sealed to be able to calculate an expiry time for the seal at a later point in time.

Each value can be entered manually during execution or can be populated as default value from a previous phase.
The values are checked against their limit configuration or expected value configuration.

Each recorded value is stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report (GID-2671587).

Anomalies that occur during processing are covered by the phase exception handling (GID-2671602)(e.g. limit violation).

After completion the phase displays the recorded values in the Execution Window.

The Navigator displays the phase completion timestamp and provides access to the post-completion exceptions.

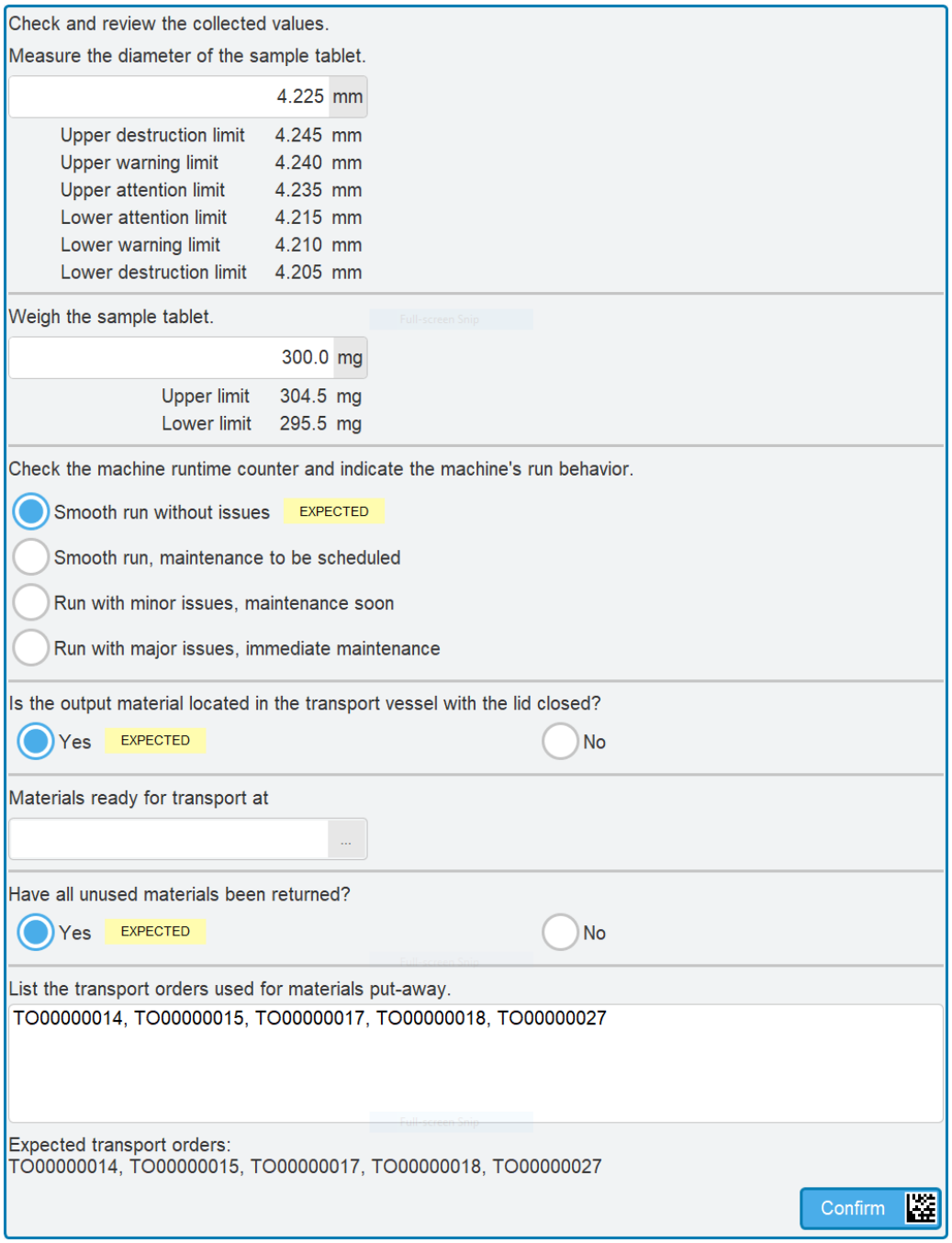


Figure 11: Get values during execution

5.1 Layout

The phase provides individual layouts for its representation during execution (GID-2669728), in the Navigator (GID-2669729), and in the sub-report (GID-2671602).

5.1.1 Representation during Execution (SR0440.1+)

The representation during execution depends on the phase mode.

5.1.1.1 GID-2671595 Preview mode (SR0440.1.1)

1. <Instruction text>
   (taken from **Instruction (SR0440.8.1)** process parameter (GID-2671622))
2. Any combination of up to ten values:
   - **Boolean Value Bundle**:
     - <Description>
       (taken from **Master (bundle identifier) (SR0440.8.14)** process parameter (GID-2671860))
     - Options (Yes, No) and default
       (taken from **Boolean options (SR0440.8.15)** process parameter (GID-2671861))
   - **Measured Value Bundle:**
     - <Description>
       (taken from **Master (bundle identifier) (SR0440.8.2)** process parameter (GID-2671866))
     - Box for <actual value, default value>
       (UoM taken from **Value Configuration (SR0440.8.3)** process parameter (GID-2671867)and default taken from **Limit definition (SR0440.8.5)** process parameter (GID-2671869))
     - Configured limits
       (taken from **Limit configuration (SR0440.8.4)** process parameter (GID-2671868)and **Limit definition (SR0440.8.5)** process parameter (GID-2671869))
       Only defined and enabled limits are displayed.
     - The **Measured value with missing Reference Value (SR0440.3.6.8)** error message text (GID-2669756)and the **Measured value with UoM configuration error (SR0440.3.6.7)** error message text (GID-2669755)inform about configuration errors detected by the **Check Measured Value Bundle Configuration (SR0440.2.15)** check (GID-2671608)as part of the phase preview.
   - **Option Value Bundle**:
     - <Description>
       (taken from **Master (bundle identifier) (SR0440.8.8)** process parameter (GID-2671872))

- List of options and default
  (taken from **List of options (SR0440.8.9)** process parameter (GID-2671873))
  Default value will be ignored if its format is invalid.

- **String Value Bundle**:
  - <Description>
    (taken from **Master (bundle identifier) (SR0440.8.20)** process parameter (GID-2671880))
  - Box for <actual text value, default value>
    (Default taken from **Expected value definition (SR0440.8.22)** process parameter (GID-2671882))
  - Configured expected value
    (taken from **Expected value configuration (SR0440.8.21)** process parameter (GID-2671881)and **Expected value definition (SR0440.8.22)** process parameter (GID-2671882))
- **Timestamp Value Bundle**:
  - <Description>
    (taken from **Master (bundle identifier) (SR0440.8.25)** process parameter (GID-2671885))
  - Box for <actual value, default value>
    Default taken from **Limit definition (SR0440.8.28)** process parameter) (GID-2671888)
  - Configured limits
    (taken from **Limit configuration (SR0440.8.27)** process parameter (GID-2671887)and **Limit definition (SR0440.8.28)** process parameter (GID-2671888))
    Only defined and enabled limits are displayed.

3. **Confirm** button (disabled).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

5.1.1.2 GID-2671596 ACTIVE MODE (SR0440.1.2)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)
2. <Instruction text>
   (taken from **Instruction (SR0440.8.1)** process parameter (GID-2671622))
3. Any combination of up to ten values:

- **Boolean Value Bundle**:
  - <Description>
    (taken from **Master (bundle identifier) (SR0440.8.14)** process parameter (GID-2671860))
  - Options (Yes, No) and default
    (taken from **Boolean options (SR0440.8.15)** process parameter (GID-2671861), editable status and default taken from the **Expected value definition (SR0440.8.17)** process parameter (GID-2671863))
- **Measured Value Bundle**:
  - <Description>
    (taken from **Master (bundle identifier) (SR0440.8.2)** process parameter (GID-2671866))
  - Box for <actual value, default value><UoM>
    (UoM taken from **Value configuration (SR0440.8.3)** process parameter (GID-2671867), editable status and default taken from **Limit definition (SR0440.8.5)** process parameter (GID-2671869))
  - Configured limits
    (taken from **Limit configuration (SR0440.8.4)** process parameter (GID-2671868)and **Limit definition (SR0440.8.5)** process parameter (GID-2671869)
    Only defined and enabled limits are displayed.
  - The **Measured value with missing Reference Value (SR0440.3.6.8)** error message text (GID-2669756)and the **Measured value with UoM configuration error (SR0440.3.6.7)** error message text (GID-2669755)inform about configuration errors detected by the **Check Measured Value Bundle Configuration (SR0440.2.15)** check (GID-2671608)as part of the active phase view.
- **Option Value Bundle**:
  - <Description>
    (taken from **Master (bundle identifier) (SR0440.8.8)** process parameter (GID-2671872))
  - List of options and default
    (taken from **List of options (SR0440.8.9)** process parameter (GID-2671873), editable status and default taken from the **Expected value definition (SR0440.8.11)** process parameter (GID-2671877))
    Default value will be ignored if its format is invalid.
- **String Value Bundle**:
  - <Description>
    (taken from **Master (bundle identifier) (SR0440.8.20)** process parameter (GID-2671880))

- Box for <actual text value, default value>
  (Editable status and default taken from **Expected value definition (SR0440.8.22)** process parameter (GID-2671882))
- Configured expected value
  (taken from **Expected value configuration (SR0440.8.21)** process parameter (GID-2671881)and **Expected value definition (SR0440.8.22)** process parameter (GID-2671882))

- **Timestamp Value Bundle**:
  - <Description>
    (taken from **Master (bundle identifier) (SR0440.8.25)** process parameter (GID-2671885))
  - Box for <actual value, default value>
    Editable default taken from **Limit definition (SR0440.8.28)** process parameter) (GID-2671888)
  - Configured limits
    (taken from **Limit configuration (SR0440.8.27)** process parameter (GID-2671887)and **Limit definition (SR0440.8.28)** process parameter (GID-2671888))
    Only defined and enabled limits are displayed.

4. **Confirm** button.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.1.1.3 GID-2671597 COMPLETED MODE (SR0440.1.3)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)
2. <Instruction text>
   (taken from **Instruction (SR0440.8.1)** process parameter (GID-2671622))
3. Table of up to five values that have been entered.
   If more than five values have been entered during execution a second table of up to five values is displayed.
   The header titles are populated from the **Short description** attributes of the related **Master (bundle identifier)** process parameter.
   - **Boolean Value Bundle**:
     Master (bundle identifier) (SR0440.8.14) process parameter (GID-2671860)
     - **Measured Value Bundle**:
       Master (bundle identifier) (SR0440.8.2) process parameter (GID-2671866)

- **Option Value Bundle**:
  Master (bundle identifier) (SR0440.8.8) process parameter (GID-2671872)
- **String Value Bundle**:
  Master (bundle identifier) (SR0440.8.20) process parameter (GID-2671880)
- **Timestamp Value Bundle**:
  Master (bundle identifier) (SR0440.8.25) process parameter (GID-2671885)

4. **Confirm** button (completed).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.1.2 Representation in Navigator (SR0440.4+)

The Navigator provides the following details:

5.1.2.1 Phase column (Framework capability)

- <Phase name>
  - Example:
    Processing values

5.1.2.2 GID-2671599 Information column (SR0440.4.1)

- <Phase completion timestamp>
  - Example: 03/03/2014 12:34:12 EDT

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

5.1.2.3 GID-2671600 Action column (SR0440.4.2)

- Correct, provides exceptions to correct the recorded values.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

5.1.3 Representation in Sub-report (SR0440.5+)

The sub-report contains the following information:

5.1.3.1 COMMON SUB-REPORT ELEMENTS (FRAMEWORK CAPABILITY)

- <Start time>
- <Completion time>
- <Unit procedure> / <operation> / <phase>
- <Work center> / <station> / <device> - <phase completion user>

5.1.3.2 GID-2671602 SUB-REPORT ELEMENTS (SR0440.5.1)

- Instruction table panel and/or instruction link panel
  (only if an instruction table and/or instruction link is defined for the phase)
- Instruction text
- Table of up to ten values that have been entered during execution.
  The header titles are populated from the **Short description** attributes of the related **Master (bundle identifier)** process parameters (**SR0440.8.2, SR0440.8.8, SR0440.8.14**, **SR0440.8.20**, **SR0440.8.25**).
- Limits and expected values are displayed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.2 Business Logic (SR0440.2+)

The phase implements the following business logic.

5.2.1 Phase Mode

Business logic related to phase modes.

5.2.1.1 GID-2671603 MANUAL COMPLETION MODE (SR0440.2.13)

- Function: **Manual completion** mode of phase
- Type: Phase mode
- Trigger: Phase becomes active
- Postcondition: Phase is active

Step	#	Description
Phase activation	10	Phase displays its user interface according to the **Active mode (SR0440.1.2)** layout (GID-2671596).
Phase completion	20	See **Confirm phase (SR0440.2.5)** function (GID-2671605).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.2.1.2 GID-2671604 Automatic completion mode (SR0440.2.14)

- Function: **Automatic completion** mode of phase
- Type: Phase mode
- Trigger: Phase becomes active
- Postcondition: Phase is completed

Step	#	Description
Phase activation	10	Phase displays its user interface according to the **Active mode (SR0440.1.2)** layout (GID-2671596).
	20	The system tries to confirm the phase immediately as if the operator had used the **Confirm** button of the phase to trigger the **Confirm phase (SR0440.2.5)** function (GID-2671605).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.2.2 Main Path

Business logic related to the main path:

5.2.2.1 GID-2671605 Confirm phase (SR0440.2.5)

- Function: Completion of phase
- Trigger: Operator confirms phase
- Postcondition: Phase is completed

Step	#	Description
Operator confirms phase	10	Operator confirms all values.
Check bundle configuration errors	12	If the phase already displays bundle configuration errors, the phase cannot be completed and the phase displays the **Bundle configuration error blocks confirm (SR0440.3.6.9)** error message (GID-2669757).
Check of required operator inputs	15	If values or selections are still missing, phase displays the **No value entered or selected (SR0440.3.6.1)** error message (GID-2669749).
Check against maximum length	16	If a string value exceeds the maximum allowed length, the phase displays the **String length exceeded (SR0440.3.6.4)** error message (GID-2669752).
Check against required format	17	If a timestamp format is violated, the phase displays the **Wrong timestamp format (SR0440.3.6.3)** error message (GID-2669751)or if a measured value format is violated, the phase displays the **Wrong measured value format (SR0440.3.6.6)** error message (GID-2669754).
Check against required precision	18	If a precision is defined for a measured value, the input value is checked against it. If the precision is violated, the phase displays the **Wrong measured value precision (SR0440.3.6.2)** error message (GID-2669750).
Lock input fields	19	Remaining editable input fields without an error are set read-only. When the combined error message from the previous checks has been confirmed, phase returns to the **Active mode (SR0440.1.2)** layout (GID-2671596). If no check failed, continue with step 20.
Final validation of values	20	If the related checks are enabled, phase triggers the **Validate Boolean Value (SR0440.2.7)** function (GID-2671607), the **Validate Measured Value (SR0440.2.2)** function (GID-2671610), the **Validate Option Value (SR0440.2.4)** function (GID-2671612), the **Validate String Value (SR0440.2.9)** function, or the **Validate Timestamp Value (SR0440.2.11)** function again for each recorded value. (This check is required because non-expected values could still be selected due to configured default values that have not yet been checked.)
	30	If none of the checks are violated or related exceptions have already been recorded, phase is completed and values are recorded.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.2.3 Boolean Value Bundle

5.2.3.1 GID-2671606 GET BOOLEAN VALUE (SR0440.2.6)

- Function: Get a Boolean Value
- Trigger: Phase becomes active
- Postcondition: Boolean Value is documented

Step	#	Description
Phase activation	10	Phase displays its user interface according to the **Active mode (SR0440.1.2)** layout (GID-2671596).
	20	▪ If no default value is set, operator can select a value. (If the value is not editable, the operator can only select a value by using the **Override value (SR0440.3.1.3)** user-triggered exception (GID-2671900).) ▪ If a default value is set and the value is editable, the operator can accept the default value or select another value. ▪ If a default value is set and the value is not editable, the operator can only accept the default value selection or override the default by using the **Override value (SR0440.3.1.3)** user-triggered exception (GID-2671900).
Operator selects Boolean Value	30	If the check is enabled according to the **Expected value configuration (SR0440.8.10)** process parameter (GID-2671876), phase triggers the **Validate Boolean Value (SR0440.2.7)** function (GID-2671607).
	40	The value selection is no longer editable, but can be updated by using the **Override value (SR0440.3.1.3)** user-triggered exception (GID-2671900).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.2.3.2 GID-2671607 VALIDATE BOOLEAN VALUE (SR0440.2.7)

- Function: Validate a Boolean Value
- Trigger: Check is enabled and operator selects a Boolean Value or phase is confirmed
- Postcondition: Boolean Value is validated

Step	#	Description
Validation	10	Phase checks the value against the settings of the **Expected value definition (SR0440.8.17)** process parameter (GID-2671863).
	20	If the check is violated, phase creates the **Violation of expected value (SR0440.3.2.3)** system-triggered exception link.
	20.1	If the **Violation of expected value (SR0440.3.2.3)** system-triggered exception (GID-2672140)is signed and recorded, the value selection is no longer editable, but can only be updated by using the **Override value (SR0440.3.1.3)** user-triggered exception (GID-2671900).
	20.2	If the **Violation of expected value (SR0440.3.2.3)** system-triggered exception (GID-2672140)is triggered upon overriding a value or the post-completion correction of a value, both exceptions are combined to one exception record, according to the **Override value (SR0440.3.1.3)** user-triggered exception (GID-2671900)or the **Correct value (SR0440.3.3.3)** post-completion exception (GID-2671913).
	30	If the check is not violated or the **Violation of expected value (SR0440.3.2.3)** system-triggered exception (GID-2672140)was signed, phase can be completed, see **Confirm phase (SR0440.2.5)** function (GID-2671605).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.2.4 Measured Value Bundle

5.2.4.1 GID-2671608 Check Measured Value bundle configuration (SR0440.2.15)

- Function: Check Measured Value bundle configuration
- Trigger: Preview or active view of phase becomes active
- Postcondition: Existing Measured Value configuration errors are displayed

Step	#	Description
Reference value check	10	If there is any limit configuration enabled, the limit type of this enabled configuration is set to **Relative**, and there is no **Reference value** defined, the phase displays the **Measured value with missing Reference Value (SR0440.3.6.8)** error message text (GID-2669756)as part of the phase view.

Step	#	Description
UoM Checks	20	The phase executes several UoM consistency checks. In case the bundle value configuration has a UoM defined ▪ a defined **Default value** must have the same or a convertible UoM defined. ▪ all defined limits with enabled limit configuration must have the same or a convertible UoM defined. ▪ a defined limit with enabled limit configuration and the **Relative** limit type requires a **Reference value** with the same or a convertible UoM. In case the bundle value configuration has no UoM defined ▪ the **Default value** cannot have a UoM defined ▪ no limit with enabled limit configuration can have a UoM defined ▪ the **Reference value** cannot have a UoM defined if any limit is defined with an enabled limit configuration and the **Relative** limit type If any of the checks fail, the phase displays the related **Measured value with UoM configuration error (SR0440.3.6.7)** error message text (GID-2669755)as part of the phase view.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.2.4.2 GID-2671609 GET MEASURED VALUE (SR0440.2.1)

- Function: Get a Measured Value
- Trigger: Phase becomes active
- Postcondition: Measured Value is documented

Step	#	Description
Bundle configuration checks	5	Phase executes the **Check Measured Value Bundle Configuration (SR0440.2.15)** check (GID-2671608)again.
Phase activation	10	Phase displays its user interface according to the **Active mode (SR0440.1.2)** layout (GID-2671596).

Step	#	Description
	20	▪ If no default value is set, the operator has to enter a value. (If the value is not editable, the operator can only enter a value by using the **Override value (SR0440.3.1.1)** user-triggered exception (GID-2671902).) ▪ If a default value is set and the value is editable, the operator accepts the default value or enters another value. ▪ If a default value is set and the value is not editable, the operator can only accept the default value or override the default by using the **Override value (SR0440.3.1.1)** user-triggered exception (GID-2671902).
Cursor leaves box	29	If a precision is defined according to the **Value configuration (SR0440.8.3)** process parameter (GID-2671867), the input value is checked against it. If the precision is violated, the phase displays the **Wrong measured value precision (SR0440.3.6.2)** error message (GID-2669750). When the error message has been confirmed, phase returns to the **Active mode (SR0440.1.2)** layout (GID-2671596). Otherwise continue with step 30. If the error is caused by a non-editable default value, it can only be corrected by using the **Override value (SR0440.3.1.1)** user-triggered exception (GID-2671902).
	30	If the check is enabled according to the **Limit configuration (SR0440.8.4)** process parameter (GID-2671868), phase triggers the **Validate Measured Value (SR0440.2.2)** function (GID-2671610).
	40	The value is no longer editable, but can be updated by using the **Override value (SR0440.3.1.1)** user-triggered exception (GID-2671902).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.2.4.3 GID-2671610 VALIDATE MEASURED VALUE (SR0440.2.2)

- Function: Validate a Measured Value
- Trigger: Check is enabled and cursor leaves the box that holds the actual value or phase is confirmed
- Postcondition: Measured Value is validated

Step	#	Description
Validation	10	Phase checks the value against the settings of the **Limit definition (SR0440.8.5)** process parameter (GID-2671902).
	20	If the limit is violated, phase creates the **Limit violation (SR0440.3.2.1)** system-triggered exception (GID-2671892).
	20.1	If the **Limit violation (SR0440.3.2.1)** system-triggered exception (GID-2671892)is signed and recorded, the box that holds the actual value is no longer editable, but can only be updated by using the **Override value (SR0440.3.1.1)** user-triggered exception (GID-2671902).
	20.2	If the **Limit violation (SR0440.3.2.1)** system-triggered exception (GID-2671892) is triggered upon overriding a value or the post-completion correction of a value, both exceptions are combined to one exception record, according to the **Override value (SR0440.3.1.1)** user-triggered exception (GID-2671902)or the **Correct value (SR0440.3.3.1)** post-completion exception (GID-2671916).
	30	If the check is not violated or the **Limit violation (SR0440.3.2.1)** system-triggered exception (GID-2671892)was signed, phase can be completed, see **Confirm phase (SR0440.2.5)** function (GID-2671605).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.2.5 Option Value Bundle

5.2.5.1 GID-2671611 Get Option Value (SR0440.2.3)

- Function: Get an Option Value
- Trigger: Phase becomes active
- Postcondition: Option Value is documented

Step	#	Description
Phase activation	10	Phase displays its user interface according to the **Active mode (SR0440.1.2)** layout (GID-2671596).
	20	▪ If no default value is set, operator can select a value. (If the value is not editable, the operator can only select a value by using the **Override value (SR0440.3.1.2)** user-triggered exception (GID-2671904).) ▪ If a default value is set and the value is editable, the operator can accept the default value or select another value. ▪ If a default value is set and the value is not editable, the operator can only accept the default value or override the default by using the **Override value (SR0440.3.1.2)** user-triggered exception (GID-2671904).
Operator selects Option Value	30	If the check is enabled according to the **Expected value configuration (SR0440.8.10)** process parameter (GID-2671876), phase triggers the **Validate Option Value (SR0440.2.4)** function (GID-2671612).
	40	The value selection is no longer editable, but can be updated by using the **Override value (SR0440.3.1.2)** user-triggered exception (GID-2671904).
Phase checks setting of **One-click completion (SR0440.8.31)** process parameter (GID-2671875)	50	If the check is enabled according to the **One-click completion (SR0440.8.31)** process parameter (GID-2671875)and the phase contains only one bundle parameter, phase is completed automatically. If an exception has occurred during the **Validate Option Value (SR0440.2.4)** function (GID-2671612), phase is not completed after the exception has been signed. Phase returns to the **Active mode (SR0080.1.2)** layout (GID-2671016)and the operator can complete the phase with the **Confirm** button.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.2.5.2 GID-2671612 VALIDATE OPTION VALUE (SR0440.2.4)

- Function: Validate an Option Value
- Trigger: Check is enabled and operator selects an Option Value or phase is confirmed
- Postcondition: Option Value is validated

Step	#	Description
Validation	10	Phase checks the value against the settings of the **Expected value definition (SR0440.8.11)** process parameter (GID-2671877).
	20	If the expected value is violated or cannot be selected at all, phase creates the **Violation of expected value (SR0440.3.2.2)** system-triggered exception (GID-2671894).
	20.1	If the **Violation of expected value (SR0440.3.2.2)** system-triggered exception (GID-2671894)is signed and recorded, the value selection is no longer editable, but can only be updated by using the **Override value (SR0440.3.1.2)** user-triggered exception (GID-2671904).
	20.2	If the **Violation of expected value (SR0440.3.2.2)** system-triggered exception (GID-2671894)is triggered upon overriding a value or the post-completion correction of a value, both exceptions are combined to one exception record, according to the **Override value (SR0440.3.1.2)** user-triggered exception (GID-2671904)or the **Correct value (SR0440.3.3.2)** post-completion exception (GID-2671919).
	30	If the check is not violated or the **Violation of expected value (SR0440.3.2.2)** system-triggered exception (GID-2671894)was signed, phase can be completed, see **Confirm phase (SR0440.2.5)** function (GID-2671605).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.2.6 String Value Bundle

5.2.6.1 GID-2671613 Get String Value (SR0440.2.8)

- Function: Get a String Value
- Trigger: Phase becomes active
- Postcondition: String Value is documented

Step	#	Description
Phase activation	10	Phase displays its user interface according to the **Active mode (SR0440.1.2)** layout (GID-2671596).
	20	▪ If no default value is set, operator can enter a value. (If the value is not editable, the operator can only enter a value by using the **Override value (SR0440.3.1.4)** user-triggered exception (GID-2671907).) ▪ If a default value is set and the value is editable, the operator can accept the default value or change the value. ▪ If a default value is set and the value is not editable, the operator can only accept the default value or override the default by using the **Override value (SR0440.3.1.4)** user-triggered exception (GID-2671907).
Cursor leaves box	29	If the value exceeds the maximum allowed length, the phase displays the **String length exceeded (SR0440.3.6.4)** error message (GID-2669752). When the error message has been confirmed, phase returns to the **Active mode (SR0440.1.2)** layout (GID-2671596). Otherwise continue with step 30. If the error is caused by a non-editable default value, it can only be corrected by using the **Override value (SR0440.3.1.4)** user-triggered exception (GID-2671907).
	30	If the check is enabled according to the **Expected value configuration (SR0440.8.21)** process parameter (GID-2671881)phase triggers the **Validate String Value (SR0440.2.9)** function (GID-2671614).
	40	The value is no longer editable, but can be updated by using the **Override value (SR0440.3.1.4)** user-triggered exception (GID-2671907).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.2.6.2 GID-2671614 VALIDATE STRING VALUE (SR0440.2.9)

- Function: Validate a String Value
- Trigger: Check is enabled and cursor leaves the box that holds the actual value or phase is confirmed
- Postcondition: String Value is validated

Step	#	Description
Validation	10	Phase checks the value against the settings of the **Expected value definition (SR0440.8.21)** process parameter (GID-2671881).
	20	If the check is violated, phase creates the **Violation of expected value (SR0440.3.2.4)** system-triggered exception (GID-2671896)
	20.1	If the **Violation of expected value (SR0440.3.2.4)** system-triggered exception (GID-2671896)is signed and recorded, the value is no longer editable, but can be updated by using the **Override value (SR0440.3.1.4)** user-triggered exception (GID-2671907).
	20.2	If the **Violation of expected value (SR0440.3.2.4)** system-triggered exception (GID-2671896)is triggered upon the post-completion correction of a value, both exceptions are combined to one exception record, according to the **Override value (SR0440.3.1.4)** user-triggered exception (GID-2671907)or the **Correct value (SR0440.3.3.4)** post-completion exception (GID-2671922).
	30	If the check is not violated or the **Violation of expected value (SR0440.3.2.4)** system-triggered exception (GID-2671896)was signed, phase can be completed, see **Confirm phase (SR0440.2.5)** function (GID-2671605).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.2.7 Timestamp Value Bundle

5.2.7.1 GID-2671615 Get Timestamp Value (SR0440.2.10)

- Function: Get a Timestamp Value
- Trigger: Phase becomes active
- Postcondition: Timestamp Value is documented

Step	#	Description
Phase activation	10	Phase displays its user interface according to the **Active mode (SR0440.1.2)** layout (GID-2671596).
	20	▪ If no default value is set, operator enters value. (If the value is not editable, the operator can only enter a value by using the **Override value (SR0440.3.1.5)** user-triggered exception (GID-2671910).) ▪ If a default value is set and the value is editable, the operator accepts the default value, enters another value, or uses the Date/Time Picker editor. ▪ If a default value is set and the value is not editable, the operator can only accept the default value or override the default by using the **Override value (SR0440.3.1.5)** user-triggered exception (GID-2671910).
Cursor leaves box or operator selects Timestamp Value with Date/Time Picker editor	29	The timestamp format is checked according the **Value configuration (SR0440.8.26)** process parameter (GID-2671886). If the format is violated, the phase displays the **Wrong timestamp format (SR0440.3.6.3)** error message (GID-2669751). When the error message has been confirmed, phase returns to the **Active mode (SR0440.1.2)** layout (GID-2671596). Otherwise continue with step 30. If the error is caused by a non-editable default value, it can only be corrected by using the **Override value (SR0440.3.1.5)** user-triggered exception (GID-2671910).
	30	If the check is enabled according to the **Limit configuration (SR0440.8.27)** process parameter (GID-2671887), phase triggers the **Validate Timestamp Value (SR0440.2.11)** function (GID-2671616).
	40	The value is no longer editable, but can be updated by using the **Override value (SR0440.3.1.5)** user-triggered exception (GID-2671910).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.2.7.2 GID-2671616 VALIDATE TIMESTAMP VALUE (SR0440.2.11)

- Function: Validate a Timestamp Value (GID-2671898)
- Trigger: Check is enabled and cursor leaves the box that holds the actual value or phase is confirmed
- Postcondition: Timestamp Value is validated

Step	#	Description
Validation	10	Phase checks the value against the settings of the **Limit definition (SR0440.8.28)** process parameter (GID-2671888).
	20	If the limit is violated, phase creates the **Limit violation (SR0440.3.2.5)** system-triggered exception (GID-2671898).
	20.1	If the **Limit violation (SR0440.3.2.5)** system-triggered exception (GID-2671898)is signed and recorded, the box that holds the actual value is no longer editable, but can be updated by using the **Override value (SR0440.3.1.5)** user-triggered exception (GID-2671910).
	20.2	If the **Limit violation (** **(GID-2671898)****)** system-triggered exception link is triggered upon overriding a value or the post-completion correction of a value, both exceptions are combined to one exception record, according to the **Override value (SR0440.3.1.5)** user-triggered exception (GID-2671910)or the **Correct value (SR0440.3.3.5)** post-completion exception (GID-2671925).
	30	If the check is not violated or the **Limit violation (SR0440.3.2.5)** system-triggered exception link was signed, phase can be completed, see **Confirm phase (SR0440.2.5)** function (GID-2671605).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.2.7.3 GID-2671617 SET VALUE WITH DATE/TIME PICKER (SR0440.2.12)

- Function: Set value with Date/Time Picker editor
- Trigger: Operator uses the **Date/Time Picker** button
- Postcondition: Timestamp Value is set

Step	#	Description
Operator uses Date/Time Picker editor	10	Phase uses the format defined by the **Value configuration (SR0440.8.26)** process parameter (GID-2671886)to set the value to the selected date and time.
	20	Checks are executed according to the **Get Timestamp Value (SR0440.2.10)** function (GID-2671615).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3 Process Parameters (SR0440.8+)

The following process parameters define the behavior of the phase.

Process parameter attributes of the **Text** type that have a maximum length definition limit the input of characters within the editor. Nevertheless, if the attribute content is defined by an expression function, a text exceeding this length is truncated to the maximum length at execution.

5.3.1 Instruction Table-specific Parameters

5.3.1.1 Instruction table definition (Framework capability)

Attribute	Type	Comment
Table layout	Choice list	Defines the layout of the instruction table holding the instruction texts. Available settings: **1 column**, **2 columns**, **3 columns**, **4 columns**, **5 columns**. Default setting: **1 column**.
First column narrow	Boolean	Defines if the first column of the table shall be narrow.
Show all borders	Boolean	Defines if the borders of the table shall be visible.

5.3.1.2 Instruction table text (Framework capability)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed in a column. **Restriction**: Maximum length is 2000 characters (including HTML tags).
Column 2	HTML text	
Column 3	HTML text	
Column 4	HTML text	
Column 5	HTML text	

5.3.2 Instruction Link-specific Parameters

5.3.2.1 Instruction text with links (Framework capability)

Attribute	Type	Comment
Instruction text	HTML text	Instruction text to be displayed. For any text enclosed in curly brackets you can define a hyperlink with the **Instruction link definition** process parameter (GID-2671621). Example: Refer to {SOP1270} for guidance. Maximum length is 2000 characters (including HTML tags).

5.3.2.2 Instruction link definition (Framework capability)

Attribute	Type	Comment
Link text	Text	Text to be used as link. For any text enclosed in curly brackets within the instruction text you can define a link with the **Link URL** attribute. Including the brackets in the link text is optional. Maximum length is 80 characters.
Link URL	Text	URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system. Maximum length is 256 characters.

5.3.3 Basic Parameters

5.3.3.1 GID-2671622 INSTRUCTION (SR0440.8.1)

Attribute	Type	Comment
Column 1	HTML text	Phase-related instruction text to be displayed during execution. **Restriction**: Maximum length is 4000 characters (including HTML tags).
Column 2	HTML text	Not used.
Column 3	HTML text	

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.3.2 GID-2671623 MODE (SR0440.8.32)

Attribute	Type	Comment
Mode	Choice list	Defines the processing mode. **Manual completion** (default): Operator confirms the phase. **Automatic completion**: Phase automatically tries to confirm the phase.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.4 Boolean Value Bundle

5.3.4.1 [BOOLEAN] BUNDLE PROCESS PARAMETERS (FRAMEWORK CAPABILITY)

For the master process parameter of a bundle, its internal identifier is populated from the bundle identifier.

For all other process parameters of the bundle, their internal identifier is a concatenation of the bundle identifier and the process parameter name.

This framework capability refers to **Bundle Process Parameters (SR3146.9.7.4.1)** in "Functional Requirement Specification Recipe and Workflow Management" [A2] (GID-2668005).

5.3.4.2 Basic Bundle Parameters

5.3.4.2.1 GID-2671860 [Boolean] Master (Bundle identifier) (SR0440.8.14)

Attribute	Type	Comment
Description	Text	Value-related instruction text to be displayed during execution. By default, the description is taken from the bundle identifier. If no description is defined, the system displays the short description; if no short description is defined, the system displays the bundle identifier. Maximum length is 250 characters.
Short description	Text	Defines the header title of the table in the **Completed mode (SR0440.1.3)** layout (GID-2671597)and, if applicable, of the linked **Show values (SR0450+)** phase (GID-2668004). Maximum length is 40 characters. Example: Hardness

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.4.2.2 GID-2671861 [Boolean] Boolean options (SR0440.8.15)

Attribute	Type	Comment
Display text for TRUE	String	Defines the string displayed as **TRUE** option. Maximum length is 8 characters. Default setting: **Yes**
Display text for FALSE	String	Defines the string displayed as **FALSE** option. Maximum length is 8 characters. Default setting: **No**

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.4.3 Configuration of System-triggered Exceptions

5.3.4.3.1 GID-2671862 [Boolean] Expected value configuration (SR0440.8.16)

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If so, ensure that the **Expected value** attribute of the **Expected value definition (SR0440.8.17)** process parameter (GID-2671863)is set.
Display	Flag	Controls if an expected value is displayed during execution if the check is enabled. The value is marked as underlined text. Ensure that the **Expected value** attribute of the **Expected value definition (SR0440.8.17)** process parameter (GID-2671863)is set.
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Violation of expected value (SR0440.3.2.3)** system-triggered exception (GID-2672140).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.4.3.2 GID-2671863 [BOOLEAN] EXPECTED VALUE DEFINITION (SR0440.8.17)

Attribute	Type	Comment
Expected value	Boolean	Defines the expected value.
Default value	Boolean	Defines the default value.
Value editable	Flag	Controls if the displayed value is editable during execution. Default setting: **Yes**

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.4.4 CONFIGURATION OF USER-TRIGGERED EXCEPTIONS

5.3.4.4.1 GID-2671864 [BOOLEAN] OVERRIDE VALUE (SR0440.8.18)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Override value (SR0440.3.1.3)** user-triggered exception (GID-2671900).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.4.5 Configuration of Post-completion Exceptions

5.3.4.5.1 GID-2671865 [Boolean] Correct value (SR0440.8.19)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Correct value (SR0440.3.3.3)** post-completion exception (GID-2671913).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.5 Measured Value Bundle

5.3.5.1 [Measured Value] Bundle process parameters (Framework capability)

For the master process parameter of a bundle, its internal identifier is populated from the bundle identifier.

For all other process parameters of the bundle, their internal identifier is a concatenation of the bundle identifier and the process parameter name.

This framework capability refers to **Bundle Process Parameters (SR3146.9.7.4.1)** in "Functional Requirement Specification Recipe and Workflow Management" [A2] (GID-2668005).

5.3.5.2 Basic Bundle Parameters

5.3.5.2.1 GID-2671866 [Measured Value] Master (Bundle identifier) (SR0440.8.2)

Attribute	Type	Comment
Description	Text	Value-related instruction text to be displayed during execution. By default, the description is taken from the bundle identifier. If no description is defined, the system displays the short description; if no short description is defined, the system displays the bundle identifier. Maximum length is 250 characters.
Short description	Text	Defines the header title of the table in the **Completed mode (SR0440.1.3)** layout (GID-2671597)and, if applicable, of the linked **Show values (SR0450+)** phase (GID-2668004). Maximum length is 40 characters. Example: Weight

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.5.2.2 GID-2671867 [MEASURED VALUE] VALUE CONFIGURATION (SR0440.8.3)

Attribute	Type	Comment
UoM	Unit of measure	Must match a unit of measure available within PharmaSuite. See also attributes of the **Limit configuration (SR0440.8.4)** process parameter (GID-2671868)and the **Limit definition (SR0440.8.5)** process parameter (GID-2671869).
Precision	Long	Optional attribute to define the scale of the value. Range: **0..9**
Value editable	Flag	Controls if the displayed value is editable during execution. Default setting: **Yes**

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.5.3 CONFIGURATION OF SYSTEM-TRIGGERED EXCEPTIONS

5.3.5.3.1 GID-2671868 [MEASURED VALUE] LIMIT CONFIGURATION (SR0440.8.4)

During execution, the actual process value is checked against the configured limits when the cursor leaves the box that holds the actual process value. If the checks are activated for the available limit ranges, the checks are performed in the following order:

1. LLL-HHH
2. LL-HH
3. L-H.

L-H configuration

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If so, ensure that the **Lower limit** or **Upper limit** attributes of the **Limit definition (SR0440.8.5)** process parameter (GID-2671869)are set.
Display	Flag	Controls if the limit range is displayed during execution if the check is enabled.
Lower limit name	Text	Defines the name of the lower limit displayed during execution. Maximum length is 64 characters.
Upper limit name	Text	Defines the name of the upper limit displayed during execution. Maximum length is 64 characters.
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 256 characters.

LL-HH configuration

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If so, ensure that the **Lower limit** or **Upper limit** attributes of the **Limit definition (SR0440.8.5)** process parameter (GID-2671869)are set.
Display	Flag	Controls if the limit range is displayed during execution if the check is enabled.
Lower limit name	Text	Defines the name of the lower limit displayed during execution. Maximum length is 64 characters.
Upper limit name	Text	Defines the name of the upper limit displayed during execution. Maximum length is 64 characters.
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 256 characters.

LLL-HHH configuration

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If so, ensure that the **Lower limit** or **Upper limit** attributes of the **Limit definition (SR0440.8.5)** process parameter (GID-2671869)are set.
Display	Flag	Controls if the limit range is displayed during execution if the check is enabled.
Lower limit name	Text	Defines the name of the lower limit displayed during execution. Maximum length is 64 characters.
Upper limit name	Text	Defines the name of the upper limit displayed during execution. Maximum length is 64 characters.
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 256 characters.

See also **Limit violation (SR0440.3.2.1)** system-triggered exception (GID-2671892).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.5.3.2 GID-2671869 [MEASURED VALUE] LIMIT DEFINITION (SR0440.8.5)

The following rules apply to the attributes:

- The unit of measure must be of the same system of measurement as the one used for the **Value configuration (SR0440.8.3)** process parameter (GID-2671867)(e.g. weight: mg, kg, pound; length: mm, m, inch).
- LLL limit < LL limit < L limit < Reference value < H limit < HH limit < HHH limit

Attribute	Type	Comment
LLL limit	MeasuredValue	Define the values of the lower limits (including the values themselves).
LL limit	MeasuredValue	
L limit	MeasuredValue	
Reference value	MeasuredValue	Defines the reference value in case of a limit range of the **Relative** limit type.
H limit	MeasuredValue	Define the values of the upper limits (including the values themselves).
HH limit	MeasuredValue	
HHH limit	MeasuredValue	
L-H type	Choice list	Define the type of the limit range (**Absolute**, **Relative**). During execution, the phase always calculates and displays absolute values. Default setting: **Absolute**.
LL-HH type	Choice list	
LLL-HHH type	Choice list	
Default value	MeasuredValue	Defines the default value.

The following limit types are available: **Absolute** and **Relative**. The limits are calculated according to the following definitions.

Limit	Absolute value definition	Relative value definition
HHH limit	HHH	Reference value + HHH
HH limit	HH	Reference value + HH
H limit	H	Reference value + H
L limit	L	Reference value - L
LL limit	LL	Reference value - LL
LLL limit	LLL	Reference value - LLL

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.5.4 Configuration of User-triggered Exceptions

5.3.5.4.1 GID-2671870 [Measured Value] Override value (SR0440.8.6)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Override value (SR0440.3.1.1)** user-triggered exception (GID-2671902).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.5.5 Configuration of Post-completion Exceptions

5.3.5.5.1 GID-2671871 [Measured Value] Correct value (SR0440.8.7)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Correct value (SR0440.3.3.1)** post-completion exception (GID-2671916).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.6 Option Value Bundle

5.3.6.1 [Option] Bundle process parameters (Framework capability)

For the master process parameter of a bundle, its internal identifier is populated from the bundle identifier.

For all other process parameters of the bundle, their internal identifier is a concatenation of the bundle identifier and the process parameter name.

This framework capability refers to **Bundle Process Parameters (SR3146.9.7.4.1)** in "Functional Requirement Specification Recipe and Workflow Management" [A2] (GID-2668005).

5.3.6.2 Basic Bundle Parameters

5.3.6.2.1 GID-2671872 [Option] Master (Bundle identifier) (SR0440.8.8)

Attribute	Type	Comment
Description	Text	Value-related instruction text to be displayed during execution. By default, the description is taken from the bundle identifier. If no description is defined, the system displays the short description; if no short description is defined, the system displays the bundle identifier. Maximum length is 250 characters.
Short description	Text	Defines the header title of the table in the **Completed mode (SR0440.1.3)** layout (GID-2671597)and, if applicable, of the linked **Show values (SR0450+)** phase (GID-2668004). Maximum length is 40 characters. Example: Appearance

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.6.2.2 GID-2671873 [Option] List of options (SR0440.8.9)

Attribute	Type	Comment
Options	Text (structured)	Defines the available options as key/display text value pairs. Both keys and display texts are unique within a phase. Maximum supported length of display text is 250 characters.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.6.2.3 Option List editor (Framework capability)

The system provides an Option List editor for entering choice items as key/display text value pairs.

5.3.6.2.4 GID-2671875 [Option] One-click completion (SR0440.8.31)

Attribute	Type	Comment
Enabled	Flag	Controls if the phase is automatically completed when an option has been selected.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.6.3 Configuration of System-triggered Exceptions

5.3.6.3.1 GID-2671876 [Option] Expected value configuration (SR0440.8.10)

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If so, ensure that the **Expected value** attribute of the **Expected value definition (SR0440.8.11)** process parameter (GID-2671877)is set.
Display	Flag	Controls if an expected value is displayed during execution if the check is enabled. The value is marked as underlined text. Ensure that the **Expected value** attribute of the **Expected value definition (SR0440.8.11)** process parameter (GID-2671877)is set.
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.

Attribute	Type	Comment
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Violation of expected value (SR0440.3.2.2)** system-triggered exception (GID-2671894).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.6.3.2 GID-2671877 [OPTION] EXPECTED VALUE DEFINITION (SR0440.8.11)

Attribute	Type	Comment
Expected value	String	Defines the expected value.
Default value	String	Defines the pre-selected item in the list of options.
Value editable	Flag	Controls if the displayed value is editable during execution. Default setting: **Yes**

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.6.4 Configuration of User-triggered Exceptions

5.3.6.4.1 GID-2671878 [Option] Override value (SR0440.8.12)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Override value (SR0440.3.1.2)** user-triggered exception (GID-2671904).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.6.5 Configuration of Post-completion Exceptions

5.3.6.5.1 GID-2671879 [Option] Correct value (SR0440.8.13)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Correct value (SR0440.3.3.2)** post-completion exception (GID-2671919).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.7 String Value Bundle

5.3.7.1 [String] Bundle process parameters (Framework capability)

For the master process parameter of a bundle, its internal identifier is populated from the bundle identifier.

For all other process parameters of the bundle, their internal identifier is a concatenation of the bundle identifier and the process parameter name.

This framework capability refers to **Bundle Process Parameters (SR3146.9.7.4.1)** in "Functional Requirement Specification Recipe and Workflow Management" [A2] (GID-2668005).

5.3.7.2 Basic Bundle Parameters

5.3.7.2.1 GID-2671880 [String] Master (Bundle identifier) (SR0440.8.20)

Attribute	Type	Comment
Description	Text	Value-related instruction text to be displayed during execution. By default, the description is taken from the bundle identifier. If no description is defined, the system displays the short description; if no short description is defined, the system displays the bundle identifier. Maximum length is 250 characters.
Short description	Text	Defines the header title of the table in the **Completed mode (SR0440.1.3)** layout (GID-2671597). Maximum length is 40 characters. Example: Start time

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.7.3 Configuration of System-triggered Exceptions

5.3.7.3.1 GID-2671881 [String] Expected value configuration (SR0440.8.21)

During execution, the actual text value is checked against the configured limits when the cursor leaves the box that holds the actual process value.

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If so, ensure that the **Expected value** attribute of the **Expected value definition (SR0440.8.22)** process parameter (GID-2671882)is set.
Display	Flag	Controls if an expected value is displayed during execution if the check is enabled.
Expected value name	Text	Defines the name of the expected value. Maximum length is 64 characters.
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 256 characters.

See also **Violation of expected value (SR0440.3.2.4)** system-triggered exception (GID-2671896).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.7.3.2 GID-2671882 [String] Expected value definition (SR0440.8.22)

Attribute	Type	Comment
Expected value	String	Defines the expected value. Maximum length is 256 characters.
Default value	String	Defines the pre-selected item in the list of options. Maximum length is 256 characters.
Value editable	Flag	Controls if the displayed value is editable during execution. Default setting: **Yes**

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.7.4 Configuration of User-triggered Exceptions

5.3.7.4.1 GID-2671883 [String] Override value (SR0440.8.23)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Override value (SR0440.3.1.4)** user-triggered exception (GID-2671907).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.7.5 Configuration of Post-completion Exceptions

5.3.7.5.1 GID-2671884 [String] Correct value (SR0440.8.24)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Correct value (SR0440.3.3.4)** post-completion exception. (GID-2671922)

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.8 Timestamp Value Bundle

5.3.8.1 [Timestamp] Bundle process parameters (Framework capability)

For the master process parameter of a bundle, its internal identifier is populated from the bundle identifier.

For all other process parameters of the bundle, their internal identifier is a concatenation of the bundle identifier and the process parameter name.

This framework capability refers to **Bundle Process Parameters (SR3146.9.7.4.1)** in "Functional Requirement Specification Recipe and Workflow Management" [A2] (GID-2668005).

5.3.8.2 Basic Bundle Parameters

5.3.8.2.1 GID-2671885 [Timestamp] Master (Bundle identifier) (SR0440.8.25)

Attribute	Type	Comment
Description	Text	Value-related instruction text to be displayed during execution. By default, the description is taken from the bundle identifier. If no description is defined, the system displays the short description; if no short description is defined, the system displays the bundle identifier. Maximum length is 250 characters.
Short description	Text	Defines the header title of the table in the **Completed mode (SR0440.1.3)** layout (GID-2671597). Maximum length is 40 characters. Example: Start time

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.8.2.2 GID-2671886 [Timestamp] Value configuration (SR0440.8.26)

Attribute	Type	Comment
Format	Choice list	Defines the format how the date and time input is required and stored. The Date/Time Picker editor uses the format to fill the input field.
Value editable	Flag	Controls if the displayed value is editable during execution. Default setting: **Yes**

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.8.3 Configuration of System-triggered Exceptions

5.3.8.3.1 GID-2671887 [Timestamp] Limit configuration (SR0440.8.27)

During execution, the actual process value is checked against the configured limits when the cursor leaves the box that holds the actual process value. If the checks are activated for the available limit ranges, the checks are performed in the following order:

1. LLL-HHH
2. LL-HH
3. L-H.

L-H configuration

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If so, ensure that the **Lower limit** or **Upper limit** attributes of the **Limit definition (SR0440.8.28)** process parameter (GID-2671888)are set.
Display	Flag	Controls if the limit range is displayed during execution if the check is enabled.
Lower limit name	Text	Defines the name of the lower limit displayed during execution. Maximum length is 64 characters.
Upper limit name	Text	Defines the name of the upper limit displayed during execution. Maximum length is 64 characters.
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 256 characters.

LL-HH configuration

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If so, ensure that the **Lower limit** or **Upper limit** attributes of the **Limit definition (SR0440.8.28)** process parameter (GID-2671888)are set.
Display	Flag	Controls if the limit range is displayed during execution if the check is enabled.
Lower limit name	Text	Defines the name of the lower limit displayed during execution. Maximum length is 64 characters.
Upper limit name	Text	Defines the name of the upper limit displayed during execution. Maximum length is 64 characters.
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 256 characters.

LLL-HHH configuration

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If so, ensure that the **Lower limit** or **Upper limit** attributes of the **Limit definition (SR0440.8.28)** process parameter (GID-2671888)are set.
Display	Flag	Controls if the limit range is displayed during execution if the check is enabled.
Lower limit name	Text	Defines the name of the lower limit displayed during execution. Maximum length is 64 characters.
Upper limit name	Text	Defines the name of the upper limit displayed during execution. Maximum length is 64 characters.
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 256 characters.

See also **Limit violation (SR0440.3.2.5)** system-triggered exception (GID-2671898).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.8.3.2 GID-2671888 [TIMESTAMP] LIMIT DEFINITION (SR0440.8.28)

The following rule applies to the attributes:

- LLL limit < LL limit < L limit < H limit < HH limit < HHH limit

Attribute	Type	Comment
LLL limit	Timestamp	Define the values of the lower limits (including the values themselves).
LL limit	Timestamp	
L limit	Timestamp	
H limit	Timestamp	Define the values of the upper limits (including the values themselves).
HH limit	Timestamp	
HHH limit	Timestamp	
Default value	Timestamp	Defines the default value.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.8.4 CONFIGURATION OF USER-TRIGGERED EXCEPTIONS

5.3.8.4.1 GID-2671889 [TIMESTAMP] OVERRIDE VALUE (SR0440.8.29)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Override value (SR0440.3.1.5)** user-triggered exception (GID-2671910).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.8.5 Configuration of Post-completion Exceptions

5.3.8.5.1 GID-2671890 [Timestamp] Correct value (SR0440.8.30)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Correct value (SR0440.3.3.5)** post-completion exception (GID-2671925).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.4 Exceptions (SR0440.3+)

The phase supports user-defined, user-triggered (GID-2669747), system-triggered (GID-2669746), and post-completion exceptions (GID-2669748)and their configuration by means of process parameters (GID-2668347).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

5.4.1 System-triggered Exceptions (SR0440.3.2+)

A system-triggered exception is represented in a message dialog along with an **Exception** button, in the Exception Window as the read-only description of the exception, and in the batch report.

The following system-triggered exceptions are available.

5.4.1.1 BOOLEAN VALUE BUNDLE

5.4.1.1.1 GID-2672140 [BOOLEAN] VIOLATION OF EXPECTED VALUE (SR0440.3.2.3)

Representation of the exception:

Exception dialog

- <Short description> or, if not maintained, <Bundle identifier>
  (taken from **Master (bundle identifier) (SR0440.8.14)** process parameter (GID-2671860))
  <Exception text>
  (taken from **Expected value configuration (SR0440.8.16)** process parameter (GID-2671862))
  Expected value: <expected value>
  Actual value: <selected value>

Exception Window

- <Short description> or, if not maintained, <Bundle identifier>
  (taken from **Master (bundle identifier) (SR0440.8.14)** process parameter (GID-2671860))
  <Exception text>
  (taken from **Expected value configuration (SR0440.8.16)** process parameter (GID-2671862))
  Expected value: <expected value>
  Actual value: <selected value>
  - Example:
    Solution dissolved?
    Expected value check failed.
    Expected value: Yes
    Actual value: No

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.1.1.2 GID-2671891 [BOOLEAN] VIOLATION OF EXPECTED VALUE - LOGIC (SR0440.3.2.3.1)

- Trigger: Operator confirms phase
- Postcondition: Exception is recorded

Step	#	Description
Operator confirms phase	10	Phase creates **Violation of expected value (SR0440.3.2.3)** system-triggered exception.
Operator triggers exception	20	Phase records the exception.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.1.2 MEASURED VALUE BUNDLE

5.4.1.2.1 GID-2671892 [MEASURED VALUE] LIMIT VIOLATION (SR0440.3.2.1)

Representation of the exception:

Exception dialog

- <Short description> or, if not maintained, <Bundle identifier>
  (taken from **Master (bundle identifier) (SR0440.8.2)** process parameter (GID-2671866))
  <Exception text>
  (taken from **Limit configuration (SR0440.8.4)** process parameter (GID-2671868))
  <Value> is outside of the range of valid values.
  The value must not be lower than <low limit> or higher than <high limit>.

Exception Window

- <Short description> or, if not maintained, <Bundle identifier>
  (taken from **Master (bundle identifier) (SR0440.8.2)** process parameter (GID-2671866))
  <Exception text>
  (taken from **Limit configuration (SR0440.8.4)** process parameter (GID-2671868))
  <Value> is outside of the range of valid values.
  The value must not be lower than <low limit> or higher than <high limit>
  - Example:
    Speed
    Limit violation confirmed
    200 rpm is outside of the range of valid values.
    The value must not be lower than 300 rpm or higher than 400 rpm.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.1.2.2 GID-2671893 [MEASURED VALUE] LIMIT VIOLATION - LOGIC (SR0440.3.2.1.1)

- Trigger: Value is not within the defined limits
- Postcondition: Exception is recorded

Step	#	Description
Operator accepts exceptional situation	10	Phase shows exception description to be signed.
Operator signs exception	20	Phase records the exception.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.1.3 OPTION VALUE BUNDLE

5.4.1.3.1 GID-2671894 [OPTION] VIOLATION OF EXPECTED VALUE (SR0440.3.2.2)

Representation of the exception:

Exception dialog

- <Short description> or, if not maintained, <Bundle identifier>
  (taken from **Master (bundle identifier) (SR0440.8.8)** process parameter (GID-2671872))
  <Exception text>
  (taken from **Expected value configuration (SR0440.8.10)** process parameter (GID-2671876))
  Expected value: <Expected text>
  Actual value: <Selected text>

Exception Window

- <Short description> or, if not maintained, <Bundle identifier>
  (taken from **Master (bundle identifier) (SR0440.8.8)** process parameter (GID-2671872))
  <Exception text>
  (taken from **Expected value configuration (SR0440.8.10)** process parameter (GID-2671876))
  Expected value: <Expected text>
  Actual value: <Selected text>
  - Example:
    Production key
    Expected value check failed.
    Expected value: B/Biotech
    Actual value: M/Microbiology

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.1.3.2 GID-2671895 [OPTION] VIOLATION OF EXPECTED VALUE - LOGIC (SR0440.3.2.2.1)

Trigger: Operator confirms phase

Postcondition: Exception is recorded

Step	#	Description
Operator confirms phase	10	Phase creates **Violation of expected value (SR0440.3.2.2)** system-triggered exception.
Operator triggers exception	20	Phase records the exception.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.1.4 STRING VALUE BUNDLE

5.4.1.4.1 GID-2671896 [STRING] VIOLATION OF EXPECTED VALUE (SR0440.3.2.4)

Representation of the exception:

Exception dialog

- <Short description> or, if not maintained, <Bundle identifier>
  (taken from **Master (bundle identifier) (SR0440.8.20)** process parameter (GID-2671880))
  <Exception text>
  (taken from **Expected value configuration (SR0440.8.21)** process parameter (GID-2671881))
  Expected value: <expected value>
  Actual value: <selected value>

Exception Window

- <Short description> or, if not maintained, <Bundle identifier>
  (taken from **Master (bundle identifier) (SR0440.8.20)** process parameter (GID-2671880))
  <Exception text>
  (taken from **Expected value configuration (SR0440.8.21)** process parameter (GID-2671881))
  Expected value: <expected value>
  Actual value: <selected value>
  - Example:
    Used filter test device

Expected value check failed.
Expected value: FTest03
Actual value: FTest09

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.1.4.2 GID-2671897 [STRING] VIOLATION OF EXPECTED VALUE - LOGIC (SR0440.3.2.4.1)

- Trigger: Operator confirms phase
- Postcondition: Exception is recorded

Step	#	Description
Operator confirms phase	10	Phase creates **Violation of expected value (SR0440.3.2.4)** system-triggered exception.
Operator triggers exception	20	Phase records the exception.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.1.5 TIMESTAMP VALUE BUNDLE

5.4.1.5.1 GID-2671898 [TIMESTAMP] LIMIT VIOLATION (SR0440.3.2.5)

Representation of the exception:

Exception dialog

- <Short description> or, if not maintained, <Bundle identifier>
  (taken from **Master (bundle identifier) (SR0440.8.25)** process parameter (GID-2671885))
  <Exception text>
  (taken from **Limit configuration (SR0440.8.27)** process parameter (GID-2671887))
  <formatted value> (<value>) is outside of the range of valid values. The value must not be before <formatted low limit> (<low limit>) and after <formatted high limit> (<high limit>).
  Full timestamp pattern: (MM/dd/yyyy hh:mm:ss a z)

Exception Window

- <Short description> or, if not maintained, <Bundle identifier>
  (taken from **Master (bundle identifier) (SR0440.8.25)** process parameter (GID-2671885))
  <Exception text>
  (taken from **Limit configuration (SR0440.8.27)** process parameter (GID-2671887))
  <formatted value> (<value>) is outside of the range of valid values. The value must not be before <formatted low limit> (<low limit>) and after <formatted high limit> (<high limit>).
  Full timestamp pattern: (MM/dd/yyyy hh:mm:ss a z)
  - Example:
    Container seal expired
    Limit violation confirmed
    12/31/2018 (12/31/2018 08:23:50 AM CET) is outside of the range of valid values. The value must not be before 12/24/2018 (12/24/2018 00:00:00 AM CET) and after 01/01/2019 (01/01/2019 11:59:59 PM CET).
    Full timestamp pattern: (MM/dd/yyyy hh:mm:ss a z)

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.1.5.2 GID-2671899 [TIMESTAMP] LIMIT VIOLATION - LOGIC (SR0440.3.2.5.1)

- Trigger: Value is not within the defined limits
- Postcondition: Exception is recorded

Step	#	Description
Operator accepts exceptional situation	10	Phase creates **Violation of expected value (SR0440.3.2.5)** system-triggered exception.
Operator signs exception	20	Phase records the exception.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.2 User-triggered Exceptions (SR0440.3.1+)

A user-triggered exception is represented in the list of available user-triggered exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following user-triggered exceptions are available.

5.4.2.1 Boolean Value Bundle

5.4.2.1.1 GID-2671900 [Boolean] Override value (SR0440.3.1.3)

The **Override value** exception allows an operator to override the value in case it is set to **read-only** (**Value editable** attribute of the **Expected value definition (SR0440.8.17)** process parameter (GID-2671863)) or was successfully validated.

Representation during exception handling:

Exception instruction

- <Short description> or, if not maintained, <Bundle identifier>
  (taken from **Master (bundle identifier) (SR0440.8.14)** process parameter (GID-2671860))
  Select another value.
  Current value <Current value>
  New value <Display options (Yes, No)>
  Confirm button.

Recorded exception

- <Short description> or, if not maintained, <Bundle identifier>
  (taken from **Master (bundle identifier) (SR0440.8.14)** process parameter (GID-2671860))
  <Exception text>
  (taken from **Override value (SR0440.8.18)** process parameter (GID-2671864))
  Current value: <Current value>
  New value: <New value>
  - Example:
    Dissolved?
    Option corrected.
    Current value: No
    New value: Yes

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.2.1.2 GID-2671901 [BOOLEAN] OVERRIDE VALUE - LOGIC (SR0440.3.1.3.1)

- Trigger: Exception is selected
- Postcondition: Value is overridden

Step	#	Description
Operator signs exception	10	Phase displays Exception Window.
	20	Operator selects another Boolean Value.
Operator confirms exception	25	If the value is equal to the old value, the phase displays the **Value not changed (SR0440.3.6.5)** error message (GID-2669753).
	30	If the related check is enabled, phase checks the value against the settings of the **Expected value definition (SR0440.8.17)** process parameter link. Phase shows exception description to be signed according to **Override value (SR0440.8.18)** process parameter (GID-2671864).
	30.1	If the expected value is violated, only one combined exception (user triggered exception) is displayed including both, exception text from the violation of the expected value and exception description to be signed according to the **Override value (SR0440.8.18)** process parameter (GID-2671864). The recorded risk of the combined exception and its required signature are controlled by the highest risk of the two underlying exceptions.
	30.2	If the expected value is not violated or no check applies, phase shows exception description to be signed according to the **Override value (SR0440.8.18)** process parameter (GID-2671864).
Operator signs exception	40	Phase records the exception.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.2.2 Measured Value Bundle

5.4.2.2.1 GID-2671902 [Measured Value] Override value (SR0440.3.1.1)

The **Override value** exception allows an operator to override the value in case it is set to **read-only** (**Value editable** attribute of the **Limit definition (SR0440.8.5)** process parameter (GID-2671869)) or was successfully validated.

Representation during exception handling:

Exception instruction

- <Short description> or, if not maintained, <Bundle identifier>
  (taken from **Master (bundle identifier) (SR0440.8.2)** process parameter (GID-2671866))
  Enter a new value.
  Current value <Current value with unit of measure>
  New value <Box for new value (with unit of measure)>
  Confirm button.

Recorded exception

- <Short description> or, if not maintained, <Bundle identifier>
  (taken from **Master (bundle identifier) (SR0440.8.2)** process parameter (GID-2671866))
  <Exception text>
  (taken from **Override value (SR0440.8.6)** process parameter (GID-2671870))
  Current value: <current value> <UoM>
  New value: <new value> <UoM>
  - Example:
    Speed
    Speed value corrected.
    Current value: 20 rpm
    New value: 25 rpm

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.2.2.2 GID-2671903 [MEASURED VALUE] OVERRIDE VALUE - LOGIC (SR0440.3.1.1.1)

- Trigger: Exception is selected
- Postcondition: Value is overridden

Step	#	Description
Operator triggers exception	10	Phase displays Exception Window.
	20	Operator enters new value.
Operator confirms exception	25	If the value is equal to the old value, the phase displays the **Value not changed (SR0440.3.6.5)** error message (GID-2669753).
	30	If a precision is defined according to the **Value configuration (SR0440.8.3)** process parameter (GID-2671867), the input value is checked against it. If the precision is violated, the phase displays the **Wrong measured value precision (SR0440.3.6.2)** error message (GID-2669750). When the error message has been confirmed, phase returns to the exception window. Otherwise continue with step 31.
	31	If the related check is enabled, phase checks the value against the settings of the **Limit definition (SR0440.8.5)** process parameter (GID-2671869).
	31.1	If the limits are violated, only one combined exception (user triggered exception) is displayed including both, exception text from the violation of the limits and the exception description to be signed according to the **Override value (SR0440.8.6)** process parameter (GID-2671870) The recorded risk of the combined exception and its required signature are controlled by the highest risk of the two underlying exceptions.
	31.2	If the limits are not violated or no check applies, phase shows the exception description to be signed according to **Override value (SR0440.8.6)** process parameter link.
Operator signs exception	40	Phase records the exception.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.2.3 Option Value Bundle

5.4.2.3.1 GID-2671904 [Option] Override value (SR0440.3.1.2)

The **Override value** exception allows an operator to override the value in case it is set to **read-only** (**Value editable** attribute of the **Expected value definition (SR0440.8.11)** process parameter (GID-2671877)) or was successfully validated.

Representation during exception handling:

Exception instruction

- <Short description> or, if not maintained, <Bundle identifier>
  (taken from **Master (bundle identifier) (SR0440.8.8)** process parameter (GID-2671872))
  Select another option.
  Current value <Current text>
  New value <Display of list of options according to the **Active mode (SR0440.1.2)** layout (GID-2671596)>
  Confirm button.

Recorded exception

- <Short description> or, if not maintained, <Bundle identifier>
  (taken from **Master (bundle identifier) (SR0440.8.8)** process parameter (GID-2671872))
  <Exception text>
  (taken from **Override value (SR0440.8.12)** process parameter (GID-2671878))
  Current value: <Current text>
  New value: <New text>
  - Example:
    Appearance
    Selection corrected.
    Current value: Yellow appearance of test strip
    New value: Blue appearance of test strip

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.2.3.2 GID-2671905 [OPTION] OVERRIDE VALUE - LOGIC (SR0440.3.1.2.1)

- Trigger: Exception is selected
- Postcondition: Value is overridden

Step	#	Description
Operator signs exception	10	Phase displays Exception Window.
	20	Operator selects another value.
Operator confirms exception	25	If the value is equal to the old value, the phase displays the **Value not changed (SR0440.3.6.5)** error message (GID-2669753).
	30	If the related check is enabled, phase checks the value against the settings of the **Expected value definition (SR0440.8.11)** process parameter (GID-2671877).
	30.1	If the expected value is violated, only one combined exception (user triggered exception) is displayed including both, exception text from the violation of the expected value and exception description to be signed according to the **Override value (SR0440.8.12)** process parameter (GID-2671878). The recorded risk of the combined exception and its required signature are controlled by the highest risk of the two underlying exceptions.
	30.2	If the expected value is not violated or no check applies, phase shows exception description to be signed according to the **Override value (SR0440.8.12)** process parameter (GID-2671878).
Operator signs exception	40	Phase records the exception.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.2.4 String Value Bundle

5.4.2.4.1 GID-2671907 [String] Override value (SR0440.3.1.4)

The **Override value** exception allows an operator to override the value in case it is set to **read-only** (**Value editable** attribute of the **Expected value definition (SR0440.8.22)** process parameter (GID-2671882)) or was successfully validated.

Representation during exception handling:

Exception instruction

- <Short description> or, if not maintained, <Bundle identifier>
  (taken from **Master (bundle identifier) (SR0440.8.20)** process parameter (GID-2671880))
  Enter a new value.
  Current value: <Current text>
  New value <Box for new value>
  Confirm button.

Recorded exception

- <Short description> or, if not maintained, <Bundle identifier>
  (taken from **Master (bundle identifier) (SR0440.8.20)** process parameter (GID-2671880))
  <Exception text>
  (taken from **Override value (SR0440.8.23)** process parameter (GID-2671883))
  Current value: <current value>
  New value: <new value>
  - Example:
    Used test equipment
    Entered value corrected.
    Current value: FTest03
    New value: FTest09

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.2.4.2 GID-2671908 [STRING] OVERRIDE VALUE - LOGIC (SR0440.3.1.4.1)

- Trigger: Exception is selected
- Postcondition: Value is overridden

Step	#	Description
Operator triggers exception	10	Phase displays Exception Window.
	20	Operator enters another value.
Operator confirms exception	25	If the value exceeds the maximum allowed length, the phase displays the **String length exceeded (SR0440.3.6.4)** error message (GID-2669752).
	26	If the value is equal to the old value, the phase displays the **Value not changed (SR0440.3.6.5)** error message (GID-2669753).
	30	If the related check is enabled, phase checks the value against the settings of the **Expected value definition (SR0440.8.22)** process parameter (GID-2671882).
	30.1	If the expected value is violated, only one combined exception (user triggered exception) is displayed including both, exception text from the violation of the expected value and exception description to be signed according to the **Override value (SR0440.8.23)** process parameter (GID-2671883). The recorded risk of the combined exception and its required signature are controlled by the highest risk of the two underlying exceptions.
	30.2	If the expected value is not violated or no check applies, phase shows exception description to be signed according to the **Override value (SR0440.8.6)** process parameter (GID-2671870).
Operator signs exception	40	Phase records the exception.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.2.5 TIMESTAMP VALUE BUNDLE

5.4.2.5.1 GID-2671910 [TIMESTAMP] OVERRIDE VALUE (SR0440.3.1.5)

The **Override value** exception allows an operator to override the value in case it is set to **read-only** (**Value editable** attribute of the **Limit definition (SR0440.8.28)** process parameter (GID-2671888)).

Representation during exception handling:

Exception instruction

- <Short description> or, if not maintained, <Bundle identifier>
  (taken from **Master (bundle identifier) (SR0440.8.25)** process parameter (GID-2671885))
  Enter a new value.
  Current value: <Current value>
  New value <Box for new value (manual input or select value from date time picker)>
  Confirm button.

Recorded exception

- <Short description> or, if not maintained, <Bundle identifier>
  (taken from **Master (bundle identifier) (SR0440.8.25)** process parameter (GID-2671885))
  <Exception text>
  (taken from **Override value (SR0440.8.29)** process parameter (GID-2671889))
  Current value: <current value>
  New value: <new value>
  - Example:
    Seal expiry date.
    Container seal expiry date correction.
    Current value: 12/24/2018 00:00:00 AM CET
    New value: 12/31/2018 08:23:50 AM CET

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.2.5.2 GID-2671911 [TIMESTAMP] OVERRIDE VALUE - LOGIC (SR0440.3.1.5.1)

- Trigger: Exception is selected
- Postcondition: Value is overridden

Step	#	Description
Operator triggers exception	10	Phase displays Exception Window.
	20	Operator enters new value or select one from the date time picker.
Operator confirms exception	25	If the value is equal to the old value, the phase displays the **Value not changed (SR0440.3.6.5)** error message (GID-2669753).
Operator confirms exception	30	A format is defined according **Value configuration (SR0440.8.26)** process parameter (GID-2671886). The input value is checked against it. If the format is violated, the phase displays the **Wrong timestamp format (SR0440.3.6.3)** error message (GID-2669751). When the error message has been confirmed, phase returns to the exception window. Otherwise continue with step 31.
	31	If the related check is enabled, phase checks the value against the settings of the **Limit definition (SR0440.8.28)** process parameter (GID-2671888).
	31.1	If the limits are violated, only one combined exception (user triggered exception) is displayed including both, exception text from the violation of the limits and the exception description to be signed according to the **Override value (SR0440.8.29)** process parameter (GID-2671889). The recorded risk of the combined exception and its required signature are controlled by the highest risk of the two underlying exceptions.
	31.2	If the limits are not violated or no check applies, phase shows exception description to be signed according to the **Override value (SR0440.8.29)** process parameter (GID-2671889).
Operator signs exception	40	Phase records the exception.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.3 Post-completion Exceptions (SR0440.3.3+)

A post-completion exception is accessible via the Navigator and represented in the list of available post-completion exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following post-completion exceptions are available.

5.4.3.1 BOOLEAN VALUE BUNDLE

5.4.3.1.1 GID-2671913 [BOOLEAN] CORRECT VALUE (SR0440.3.3.3)

The **Correct value** exception allows an operator to correct the recorded value from the Navigator after the completion of the phase.

> **TIP**
>
> A recorded value could be used within branching. The correction of a value **does not influence** already processed branching decisions.

Representation of the exception:

Exception instruction

- <Short description> or, if not maintained, <Bundle identifier>
  (taken from **Master (bundle identifier) (SR0440.8.14)** process parameter (GID-2671860))
  Select another value.
  Current value <Current value>
  New value <Display options (Yes, No)>
  Confirm button.

Recorded exception

- <Short description> or, if not maintained, <Bundle identifier>
  (taken from **Master (bundle identifier) (SR0440.8.14)** process parameter (GID-2671860))
  <Exception text>
  (taken from **Override value (SR0440.8.19)** process parameter (GID-2671865))
  Old value: <Old value>
  New value: <New value>
  - Example:
    Dissolved?
    Option corrected (after phase completion).
    Old value: No
    New value: Yes

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.3.1.2 GID-2671914 [BOOLEAN] CORRECT VALUE - LOGIC (SR0440.3.3.3.1)

Trigger: Phase is completed

Postcondition: Value is corrected

Step	#	Description
Operator triggers action	10	Phase displays Exception Window.
	20	Operator selects corrected value.
Operator confirms exception	25	If the value is equal to the old value, the phase displays the **Value not changed (SR0440.3.6.5)** error message (GID-2669753).
	30	If the related check is enabled, phase checks the value against the settings of the **Expected value definition (SR0440.8.17)** process parameter (GID-2671863).
	30.1	If the expected value is violated, only one combined exception (post-completion exception) is displayed including both, exception text from the correction and from the violation of the expected value. The recorded risk of the combined exception and its required signature are controlled by the highest risk of the two underlying exceptions.
	30.2	If the expected value is not violated or no check applies, the corrected value-related exception is displayed.
Operator signs exception	40	Phase records the new value and its related exception.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.3.2 Measured Value Bundle

5.4.3.2.1 GID-2671916 [Measured Value] Correct value (SR0440.3.3.1)

The **Correct value** exception allows an operator to correct the recorded value from the Navigator after the completion of the phase.

> **TIP**
>
> A recorded value could be used within branching. The correction of a value **does not influence** already processed branching decisions.

Representation of the exception:

Exception instruction

- <Short description> or, if not maintained, <Bundle identifier>
  (taken from **Master (bundle identifier) (SR0440.8.2)** process parameter (GID-2671866))
  Enter a new value.
  Current value <Current value with unit of measure>
  New value <Box for new value (with unit of measure)>
  Confirm button.

Recorded exception

- <Short description> or, if not maintained, <Bundle identifier>
  (taken from **Master (bundle identifier) (SR0440.8.2)** process parameter (GID-2671866))
  <Exception text>
  (taken from **Correct value (SR0440.8.7)** process parameter (GID-2671871))
  Old value: <Old value> <UoM>
  New value: <New value> <UoM>
  - Example:
    Speed
    Speed value corrected (after phase completion).
    Old value: 20 rpm
    New value: 25 rpm

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.3.2.2 GID-2671917 [MEASURED VALUE] CORRECT VALUE - LOGIC (SR0440.3.3.1.1)

- Trigger: Phase is completed
- Postcondition: Value is corrected

Step	#	Description
Operator triggers action	10	Phase displays Exception Window.
	20	Operator enters corrected value.
Operator confirms exception	25	If the value is equal to the old value, the phase displays the **Value not changed (SR0440.3.6.5)** error message (GID-2669753).
	29	If a precision is defined according to the **Value configuration (SR0440.8.3)** process parameter (GID-2671867)), the input value is checked against it. If the precision is violated, the phase displays the **Wrong measured value precision (SR0440.3.6.2)** error message (GID-2669750). When the error message has been confirmed, phase returns to the exception window. Otherwise continue with step 30.
	30	If the related check is enabled, phase checks the value against the settings of the **Limit definition (SR0440.8.5)** process parameter (GID-2671869).
	30.1	If the limit is violated, only one combined exception (post-completion exception) is displayed including both, exception text from the correction and from the limit violation. The recorded risk of the combined exception and its required signature are controlled by the highest risk of the two underlying exceptions.
	30.2	If the limit is not violated or no check applies, the corrected value-related exception is displayed.
Operator signs exception	40	Phase records the new value and its related exception.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.3.3 Option Value Bundle

5.4.3.3.1 GID-2671919 [Option] Correct value (SR0440.3.3.2)

The **Correct value** exception allows an operator to correct the selected value from the Navigator after the completion of the phase.

> **TIP**
>
> A recorded value could be used within branching. The correction of a value **does not influence** already processed branching decisions.

Representation of the exception:

Exception instruction

- <Short description> or, if not maintained, <Bundle identifier>
  (taken from **Master (bundle identifier) (SR0440.8.8)** process parameter (GID-2671872))
  Select another option.
  Current value <Current text>
  New value <Display of list of options according to the **Active mode (SR0440.1.2)** layout (GID-2671596)>
  Confirm button.

Recorded exception

- <Short description> or, if not maintained, <Bundle identifier>
  (taken from **Master (bundle identifier) (SR0440.8.8)** process parameter (GID-2671872))
  <Exception text>
  (taken from **Correct value ((GID-2671879))** process parameter link)
  Old key/text: <Old key>/<Old text>
  New key/text: <New key>/<New text>
  - Example:
    Appearance
    Selection corrected (after phase completion).
    Old key/text: Yellow/Yellow appearance of test strip
    New key/text: Blue/Blue appearance of test strip

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.3.3.2 GID-2671920 [OPTION] CORRECT VALUE - LOGIC (SR0440.3.3.2.1)

- Trigger: Phase is completed
- Postcondition: Value is corrected

Step	#	Description
Operator triggers action	10	Phase displays Exception Window.
	20	Operator selects corrected value.
Operator confirms exception	25	If the value is equal to the old value, the phase displays the **Value not changed (SR0440.3.6.5)** error message (GID-2669753).
	30	If the related check is enabled, phase checks the value against the settings of the **Expected value definition (SR0440.8.11)** process parameter (GID-2671877).
	30.1	If the expected value is violated, only one combined exception (post-completion exception) is displayed including both, exception text from the correction and from the violation of the expected value. The recorded risk of the combined exception and its required signature are controlled by the highest risk of the two underlying exceptions.
	30.2	If the expected value is not violated or no check applies, the corrected value-related exception is displayed.
Operator signs exception	40	Phase records the new value and its related exception.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.3.4 String Value Bundle

5.4.3.4.1 GID-2671922 [String] Correct value (SR0440.3.3.4)

The **Correct value** exception allows an operator to correct the recorded value from the Navigator after the completion of the phase.

> **TIP**
>
> A recorded value could be used within branching. The correction of a value **does not influence** already processed branching decisions.

Representation of the exception:

Exception instruction

- <Short description> or, if not maintained, <Bundle identifier>
  (taken from **Master (bundle identifier) (SR0440.8.20)** process parameter (GID-2671880))
  Enter a new value.
  Current value: <Current text>
  New value <Box for new value>
  Confirm button.

Recorded exception

- <Short description> or, if not maintained, <Bundle identifier>
  (taken from **Master (bundle identifier) (SR0440.8.8)** process parameter (GID-2671872))
  <Exception text>
  (taken from **Correct value (SR0440.8.24)** process parameter (GID-2671884))
  Old value: <Old value>
  New value: <New value>
  - Example:
    Used test equipment
    Entered value corrected.
    Old value: FTest03
    New value: FTest09

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.3.4.2 GID-2671923 [STRING] CORRECT VALUE - LOGIC (SR0440.3.3.4.1)

- Trigger: Phase is completed
- Postcondition: Value is corrected

Step	#	Description
Operator triggers action	10	Phase displays Exception Window.
	20	Operator enters corrected value.
Operator confirms exception	25	If the value exceeds the maximum allowed length, the phase displays the **String length exceeded (SR0440.3.6.4)** error message (GID-2669752).
	26	If the value is equal to the old value, the phase displays the **Value not changed (SR0440.3.6.5)** error message (GID-2669753).
	30	If the related check is enabled, phase checks the value against the settings of the **Expected value definition (SR0440.8.22)** process parameter (GID-2671882).
	30.1	If the expected value is violated, only one combined exception (post-completion exception) is displayed including both, exception text from the violation of the expected value and exception description to be signed according to the **Correct value (SR0440.8.24)** process parameter (GID-2671884) The recorded risk of the combined exception and its required signature are controlled by the highest risk of the two underlying exceptions.
	30.2	If the expected value is not violated or no check applies, phase shows exception description to be signed according to the **Correct value (SR0440.8.24)** process parameter (GID-2671884).
Operator signs exception	40	Phase records the new value and its related exception.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.3.5 TIMESTAMP VALUE BUNDLE

5.4.3.5.1 GID-2671925 [TIMESTAMP] CORRECT VALUE (SR0440.3.3.5)

The **Correct value** exception allows an operator to correct the recorded value from the Navigator after the completion of the phase.

> **TIP**
>
> A recorded value could be used within branching. The correction of a value **does not influence** already processed branching decisions.

Representation of the exception:

Exception instruction

- <Short description> or, if not maintained, <Bundle identifier>
  (taken from **Master (bundle identifier) (SR0440.8.25)** process parameter (GID-2671885))
  Enter a new value.
  Current value: <Current value>
  New value <Box for new value (manual input or select value from date time picker)>
  Confirm button.

Recorded exception

- <Short description> or, if not maintained, <Bundle identifier>
  (taken from **Master (bundle identifier) (SR0440.8.25)** process parameter (GID-2671885))
  <Exception text>
  (taken from **Correct value (SR0440.8.30)** process parameter (GID-2671890))
  Old value: <Old value>
  New value: <New value>
  - Example:
    Seal expiry date.
    Container seal expiry date correction.
    Old value: 12/24/2018 00:00:00 AM CET
    New value: 12/31/2018 08:23:50 AM CET

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.3.5.2 GID-2671926 [TIMESTAMP] CORRECT VALUE - LOGIC (SR0440.3.3.5.1)

- Trigger: Phase is completed
- Postcondition: Value is corrected

Step	#	Description
Operator triggers action	10	Phase displays Exception Window.
	20	Operator enters corrected value.
Operator confirms exception	25	If the value is equal to the old value, the phase displays the **Value not changed (SR0440.3.6.5)** error message (GID-2669753).
	30	A format is defined according **Value configuration (SR0440.8.26)** process parameter (GID-2671886). The input value is checked against it. If the format is violated, the phase displays the **Wrong timestamp format (SR0440.3.6.3)** error message (GID-2669751). When the error message has been confirmed, phase returns to the exception window. Otherwise continue with step 31.
	31	If the related check is enabled, phase checks the value against the settings of the **Limit definition (SR0440.8.28)** process parameter (GID-2671888).
	31.1	If the limits are violated, only one combined exception (user triggered exception) is displayed including both, exception text from the violation of the limits and the exception description to be signed according to the **Override value (SR0440.8.29)** process parameter (GID-2671889). The recorded risk of the combined exception and its required signature are controlled by the highest risk of the two underlying exceptions.
	31.2	If the limits are not violated or no check applies, phase shows exception description to be signed according to the **Override value (SR0440.8.29)** process parameter (GID-2671889).
Operator signs exception	40	Phase records the new value and its related exception.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.5 Information Messages

There are no information messages available.

5.6 Questions

There are no questions available.

5.7 Decisions

There are no decisions available.

5.8 Error Messages (SR0440.3.6+)

Error messages are represented as part of the phase view or in an error message dialog containing a message type-specific icon, the error message, and an **OK** button.

The following error messages are available to inform the operator about error conditions.

5.8.1 GID-2669749 No value entered or selected (SR0440.3.6.1)

UI text	Comment
<Short description> (or, if not maintained, <Bundle identifier>, taken from **Master (bundle identifier)** You have to enter or select a value before you can confirm the phase.	Message pack: PhaseGetValues<version> Message ID: EmptyValue_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.8.2 GID-2669750 Wrong measured value precision (SR0440.3.6.2)

UI text	Comment
<Information that the current value does not provide the expected precision.>	Message pack: PhaseGetValues<version> Message ID: MVPrecisionViolation_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.8.3 GID-2669751 Wrong timestamp format (SR0440.3.6.3)

UI text	Comment
<Information that the current value does not conform to the expected timestamp format.>	Message pack: PhaseGetValues<version> Message ID: InvalidValue_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.8.4 GID-2669752 String length exceeded (SR0440.3.6.4)

UI text	Comment
<Information that the current value exceeds the maximum length.>	Message pack: PhaseGetValues<version> Message ID: TextRangeViolation_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.8.5 GID-2669753 Value not changed (SR0440.3.6.5)

UI text	Comment
<Information that the current value is the same as the original value.>	Message pack: PhaseGetValues<version> Message ID: SameValue_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.8.6 GID-2669754 Wrong measured value format (SR0440.3.6.6)

UI text	Comment
<Information that the current value is not expected, e.g. non-numeric input.>	Message pack: PhaseGetValues<version> Message ID: InvalidValue_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.8.7 GID-2669755 Measured value with UoM configuration error (SR0440.3.6.7)

UI text	Comment
The value (<value>) of the <bundle attribute> cannot be converted to the UoM (<UoM>) defined in the Value configuration parameter.	Message pack: PhaseGetValues<version> Message ID: CannotConvertToDefaultUom_ErrorMsg
The UoM of the Value configuration parameter is not set but the value (<value>) of the <bundle attribute> has a UoM defined.	Message pack: PhaseGetValues<version> Message ID: DefaultUomNotSet_ErrorMsg
Within execution the above error cases are extended by: Please use the Repair function to correct the issue or abort the phase.	Message pack: PhaseGetValues<version> Message ID: RepairOrAbort_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.8.8 GID-2669756 Measured value with missing Reference Value (SR0440.3.6.8)

UI text	Comment
There is no Reference value defined.	Message pack: PhaseGetValues<version> Message ID: NoReferenceValue_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.8.9 GID-2669757 Bundle Configuration Error Blocks Confirm (SR0440.3.6.9)

UI text	Comment
Cannot confirm the phase. One or more bundles have configuration errors. Please use the Repair function to correct the issue or abort the phase.	Message pack: PhaseGetValues<version> Message ID: CannotConfirmWrongConfig_ErrorMsg, RepairOrAbort_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.9 Output Variables (SR0440.9+)

The following output variables are available to reference the phase's output.

5.9.1 Instance count (Framework capability)

- Data type: Long
- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.
  The count variable of a phase that has not been executed provides 0 as output value.

5.9.2 Start time (Framework capability)

- Data type: Timestamp
- Usage: The output variable provides the start time of the phase.

5.9.3 Completion time (Framework capability)

- Data type: Timestamp

- Usage: The output variable provides the completion time of the phase.

5.9.4 Identifier (Framework capability)

- Data type: String
- Usage: The output variable provides the identifier of the phase.

5.9.5 GID-2669762 Data reference (SR0440.9.7)

- Data type: PhaseDataReference
- Usage: The output variable provides a reference to a data collection phase.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.9.6 Boolean Value Bundle

5.9.6.1 [Boolean] Bundle output variable (Framework capability)

For all output variables of the same bundle, the output variable identifier is a concatenation of the bundle identifier and the output variable name.

This framework capability refers to **Bundle Output Variable (SR3146.9.7.4.2)** in "Functional Requirement Specification Recipe and Workflow Management" [A2] (GID-2668005).

5.9.6.2 GID-2671928 [Boolean] Option text (SR0440.9.5)

- Data type: String
- Usage: The output variable provides the display text of the selected option.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.9.6.3 GID-2671929 [Boolean] Option key (SR0440.9.6)

- Data type: Boolean
- Usage: The output variable provides the selected boolean option.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.9.7 Measured Value Bundle

5.9.7.1 [Measured Value] Bundle output variable (Framework capability)

For all output variables of the same bundle, the output variable identifier is a concatenation of the bundle identifier and the output variable name.

This framework capability refers to **Bundle Output Variable (SR3146.9.7.4.2)** in "Functional Requirement Specification Recipe and Workflow Management" [A2] (GID-2668005).

5.9.7.2 GID-2671931 [Measured Value] Value (SR0440.9.1)

- Data type: MeasuredValue
- Usage: The output variable provides the complete process value as a **MeasuredValue** object.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.9.7.3 GID-2671932 [Measured Value] Unit of measure (SR0440.9.2)

- Data type: String
- Usage: The output variable provides the unit of measure of the process value.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.9.8 Option Value Bundle

5.9.8.1 [Option] Bundle output variable (Framework capability)

For all output variables of the same bundle, the output variable identifier is a concatenation of the bundle identifier and the output variable name.

This framework capability refers to **Bundle Output Variable (SR3146.9.7.4.2)** in "Functional Requirement Specification Recipe and Workflow Management" [A2] (GID-2668005).

5.9.8.2 GID-2671934 [Option] Option text (SR0440.9.3)

- Data type: String
- Usage: The output variable provides the display text of the selected option.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.9.8.3 GID-2671935 [OPTION] OPTION KEY (SR0440.9.4)

- Data type: String
- Usage: The output variable provides the key value of the selected option.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.9.9 String Value Bundle

5.9.9.1 [STRING] BUNDLE OUTPUT VARIABLE (FRAMEWORK CAPABILITY)

For all output variables of the same bundle, the output variable identifier is a concatenation of the bundle identifier and the output variable name.

This framework capability refers to **Bundle Output Variable (SR3146.9.7.4.2)** in "Functional Requirement Specification Recipe and Workflow Management" [A2] (GID-2668005).

5.9.9.2 GID-2671937 [STRING] VALUE (SR0440.9.8)

- Data type: String
- Usage: The output variable provides the text value entered during execution as string of characters.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.9.10 Timestamp Value Bundle

5.9.10.1 [TIMESTAMP] BUNDLE OUTPUT VARIABLE (FRAMEWORK CAPABILITY)

For all output variables of the same bundle, the output variable identifier is a concatenation of the bundle identifier and the output variable name.

This framework capability refers to **Bundle Output Variable (SR3146.9.7.4.2)** in "Functional Requirement Specification Recipe and Workflow Management" [A2] (GID-2668005).

5.9.10.2 GID-2671939 [TIMESTAMP] TIMESTAMP OBJECT (SR0440.9.9)

- Data type: Timestamp
- Usage: The output variable provides the entered date and time.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.9.10.3 GID-2671940 [TIMESTAMP] TIMESTAMP STRING (SR0440.9.10)

- Data type: String
- Usage: The output variable provides the entered date and time as formatted string according to the **Value configuration (SR0440.8.26)** process parameter (GID-2671886).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6 Show Values Phase (SR0450+)

The **Show values** phase allows an operator to view the data that has been collected along with the **Get values** phase (GID-2668003)across multiple runs, which are based on loops or ETO templates. The data is represented in a table format and supports up to two table sets with up to five columns with values of the following data types:

- Measured Value (measured value): value and unit of measure,
- Option Value: choice from a pre-defined list of options
- Boolean Value: choice between Yes and No (true and false)
- String Value: multi-line text, and
- Timestamp Value: date and time value in a format defined with the **Get values** phase.

Example use cases are:

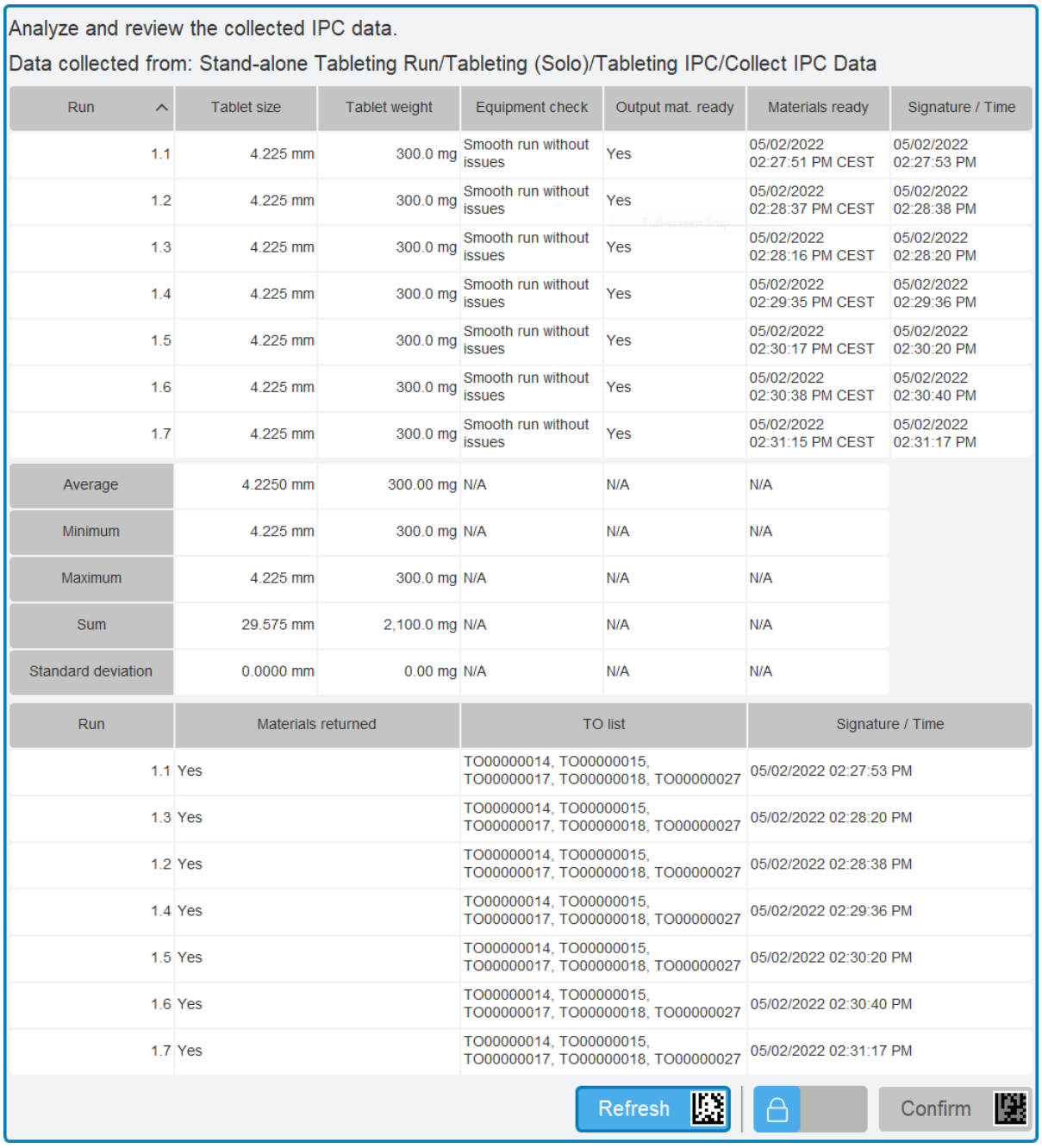
- Recording of tablet weights across multiple IPC runs.
- Recording of visual appearance across multiple IPC runs (e.g., Transparent, Cloudy, Dark).
- Recording of the execution of mandatory checks across multiple IPC runs.

For Measured Values, the result of statistical calculations can be presented as well, like Average, Min, Max, Sum, and Standard Deviation.

All data is stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report (GID-2669770).

After completion the phase displays the data in the Execution Window.

The Navigator displays the phase completion timestamp.



Run	Tablet size	Tablet weight	Equipment check	Output mat. ready	Materials ready	Signature / Time
1.1	4.225 mm	300.0 mg	Smooth run without issues	Yes	05/02/2022 02:27:51 PM CEST	05/02/2022 02:27:53 PM
1.2	4.225 mm	300.0 mg	Smooth run without issues	Yes	05/02/2022 02:28:37 PM CEST	05/02/2022 02:28:38 PM
1.3	4.225 mm	300.0 mg	Smooth run without issues	Yes	05/02/2022 02:28:16 PM CEST	05/02/2022 02:28:20 PM
1.4	4.225 mm	300.0 mg	Smooth run without issues	Yes	05/02/2022 02:29:35 PM CEST	05/02/2022 02:29:36 PM
1.5	4.225 mm	300.0 mg	Smooth run without issues	Yes	05/02/2022 02:30:17 PM CEST	05/02/2022 02:30:20 PM
1.6	4.225 mm	300.0 mg	Smooth run without issues	Yes	05/02/2022 02:30:38 PM CEST	05/02/2022 02:30:40 PM
1.7	4.225 mm	300.0 mg	Smooth run without issues	Yes	05/02/2022 02:31:15 PM CEST	05/02/2022 02:31:17 PM
Average	4.2250 mm	300.00 mg	N/A	N/A	N/A	
Minimum	4.225 mm	300.0 mg	N/A	N/A	N/A	
Maximum	4.225 mm	300.0 mg	N/A	N/A	N/A	
Sum	29.575 mm	2,100.0 mg	N/A	N/A	N/A	
Standard deviation	0.0000 mm	0.00 mg	N/A	N/A	N/A	

Run	Materials returned	TO list	Signature / Time
1.1	Yes	TO00000014, TO00000015, TO00000017, TO00000018, TO00000027	05/02/2022 02:27:53 PM
1.3	Yes	TO00000014, TO00000015, TO00000017, TO00000018, TO00000027	05/02/2022 02:28:20 PM
1.2	Yes	TO00000014, TO00000015, TO00000017, TO00000018, TO00000027	05/02/2022 02:28:38 PM
1.4	Yes	TO00000014, TO00000015, TO00000017, TO00000018, TO00000027	05/02/2022 02:29:36 PM
1.5	Yes	TO00000014, TO00000015, TO00000017, TO00000018, TO00000027	05/02/2022 02:30:20 PM
1.6	Yes	TO00000014, TO00000015, TO00000017, TO00000018, TO00000027	05/02/2022 02:30:40 PM
1.7	Yes	TO00000014, TO00000015, TO00000017, TO00000018, TO00000027	05/02/2022 02:31:17 PM

Figure 12: Show values during execution

6.1 Layout

The phase provides individual layouts for its representation during execution (GID-2669768), in the Navigator (GID-2669769), and in the sub-report (GID-2669770).

6.1.1 Representation during Execution (SR0450.1+)

The representation during execution depends on the phase mode.

6.1.1.1 GID-2671941 Preview mode (SR0450.1.1)

1. <Instruction text>
   (taken from **Instruction (SR0450.8.1)** process parameter (GID-2671953))
2. Data collected from:
   (no path information available during preview)
3. Empty table header for value-related columns
4. Empty table with statistics-related rows
   (according to the **Master (bundle identifier) (SR0450.8.3)** process parameter (GID-2671956))
5. **Refresh** button (disabled)
6. **Enable** button (disabled).
   The button is not visible in case a phase completion signature was configured during authoring.
7. **Confirm** button (disabled).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

6.1.1.2 GID-2671942 Active mode (SR0450.1.2)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)
2. <Instruction text>
   (taken from **Instruction (SR0450.8.1)** process parameter (GID-2671953))
3. Data collected from: <Path information of referred **Get values** phase>
4. First table of values with **Run** column, up to five value-related columns, and **Signature / Time** column.
   (Header titles of the value-related columns are populated from the **Get values (SR0440+)** phase (GID-2668003)that is referenced by the **Data collection reference** attribute of the **Definition (SR0450.8.2)** process parameter (GID-2671954)and from the **Short description** attributes of the related **Master (bundle identifier)** process parameters (**SR0440.8.2**, **SR0440.8.8**, **SR0440.8.14**, **SR0440.8.20**, **SR0440.8.25**).
   Signature / Time values are populated from the completion times of the **Get values** phase.)

5. First table with statistical data.
   (Visibility is controlled by the **Master (bundle identifier) (SR0450.8.3)** process parameter (GID-2671956).)
6. Second table of values with **Run** column, up to five value-related columns, and **Signature / Time** column.
   (Header titles of the value-related columns are populated from the **Get values (SR0440+)** phase (GID-2668003)) that is referenced by the **Data collection reference** attribute of the **Definition (SR0450.8.2)** process parameter (GID-2671954)and from the **Short description** attributes of the related **Master (bundle identifier)** process parameters (**SR0440.8.2**, **SR0440.8.8**, **SR0440.8.14**, **SR0440.8.20**, **SR0440.8.25**).
   Signature / Time values are populated from the completion times of the **Get values** phase.)
7. Second table with statistical data.
   (Visibility is controlled by the **Master (bundle identifier) (SR0450.8.3)** process parameter (GID-2671956).)
8. **Refresh** button
9. **Enable** button (unlocks the **Confirm** button).
   The button is not visible in case a phase completion signature was configured during authoring.
10. **Confirm** button.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.1.1.3 GID-2671943 COMPLETED MODE (SR0450.1.3)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)
2. <Instruction text>
   (taken from **Instruction (SR0450.8.1)** process parameter (GID-2671953))
3. Data collected from: <Path information of referred **Get values** phase>
4. First table of values with **Run** column, up to five value-related columns, and **Signature / Time** column.
   (Header titles of the value-related columns are populated from the **Get values (SR0440+)** phase (GID-2668003)that is referenced by the **Data collection reference** attribute of the **Definition (SR0450.8.2)** process parameter (GID-2671954)and from the **Short description** attributes of the related **Master (bundle identifier)** process parameters (**SR0440.8.2**, **SR0440.8.8**, **SR0440.8.14**, **SR0440.8.20**, **SR0440.8.25**).
   Signature / Time values are populated from the completion times of the **Get values** phase.)

5. First table with statistical data.
   (Visibility is controlled by the **Master (bundle identifier) (SR0450.8.3)** process parameter (GID-2671956).)
6. Second table of values with **Run** column, up to five value-related columns, and **Signature / Time** column.
   (Header titles of the value-related columns are populated from the **Get values (SR0440+)** phase (GID-2668003)that is referenced by the **Data collection reference** attribute of the **Definition (SR0450.8.2)** process parameter (GID-2671954)and from the **Short description** attributes of the related **Master (bundle identifier)** process parameters (**SR0440.8.2**, **SR0440.8.8**, **SR0440.8.14**, **SR0440.8.20**, **SR0440.8.25**).
   Signature / Time values are populated from the completion times of the **Get values** phase.)
7. Second table with statistical data.
   (Visibility is controlled by the **Master (bundle identifier) (SR0450.8.3)** process parameter (GID-2671956).)
8. **Refresh** button (disabled)
9. **Enable** button (disabled).
   The button is not visible in case a phase completion signature was configured during authoring.
10. **Confirm** button (completed).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.1.2 Representation in Navigator (SR0450.4+)

The Navigator provides the following details:

6.1.2.1 Phase column (Framework capability)

- <Phase name>
  - Example:
    Hardness trend

6.1.2.2 GID-2671945 Information column (SR0450.4.1)

- <Phase completion timestamp>
- >Example: 03/03/2014 12:34:12 EDT

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

6.1.2.3 Action column

- There are no phase-specific actions available.

6.1.3 Representation in Sub-report (SR0450.5+)

The sub-report contains the following information:

6.1.3.1 Common sub-report elements (Framework capability)

- <Start time>
- <Completion time>
- <Unit procedure> / <operation> / <phase>
- <Work center> / <station> / <device> - <phase completion user>

6.1.3.2 GID-2671948 Sub-report elements (SR0450.5.1)

- Instruction table panel and/or instruction link panel
  (only if an instruction table and/or instruction link is defined for the phase)
- Instruction text
- Data collected from: <Path information of referred **Get values** phase>
- First table of values with **Run** column, up to five value-related columns, and **Signature / Time** column.
  (Header titles of the value-related columns are populated from the **Get values (SR0440+)** phase (GID-2668003)that is referenced by the **Data collection reference** attribute of the **Definition (SR0450.8.2)** process parameter (GID-2671954)and from the **Short description** attributes of the related **Master (bundle identifier)** process parameters (**SR0440.8.2**, **SR0440.8.8**, **SR0440.8.14**, **SR0440.8.20**, **SR0440.8.25**).
  Signature / Time values are populated from the completion times of the **Get values** phase.)
- First table with statistical data.
  (Visibility is controlled by the **Master (bundle identifier) (SR0450.8.3)** process parameter (GID-2671956).)
- Second table of values with **Run** column, up to five value-related columns, and **Signature / Time** column.
  (Header titles of the value-related columns are populated from the **Get values (SR0440+)** phase (GID-2668003)that is referenced by the **Data collection reference** attribute of the **Definition (SR0450.8.2)** process parameter (GID-2671954)and from the **Short description** attributes of the related **Master (bundle identifier)** process parameters (**SR0440.8.2**, **SR0440.8.8**, **SR0440.8.14**, **SR0440.8.20**, **SR0440.8.25**).
  Signature / Time values are populated from the completion times of the **Get values** phase.)
- Second table with statistical data.
  (Visibility is controlled by the **Master (bundle identifier) (SR0450.8.3)** process parameter (GID-2671956).)

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.2 Business Logic (SR0450.2+)

The phase implements the following business logic.

6.2.1 GID-2669771 Phase activation (SR0450.2.1)

- Function: Phase is active
- Trigger: Previous phase is completed
- Postcondition: Phase is active

Step	#	Description
Phase is activated	10	Phase checks if data from the data collection reference phase and its instances is already available.
	10.1	If no data is available, the table of values and the table of statistics still remain empty. With **Refresh**, phase checks again if data is available, according to step 10.
	10.2	If data is available, phase displays the table of values and the table of statistics according to the Active mode (SR0450.1.2) layout (GID-2671942). ▪ In case the referenced **Get values** phase was completed with a phase completion signature, phase displays this signature and its timestamp in the **Signature / Time** column. ▪ In case the referenced **Get values** phase was completed without a signature, phase displays the phase completion timestamp in the **Signature / Time** column.
Phase is refreshed	20	With **Refresh**, phase adds more run-related data, if available, and recalculates the statistical values.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.2.2 GID-2669772 Statistics calculation (SR0450.2.2)

- Function: Calculate statistics
- Trigger: Phase is activated or refreshed
- Postcondition: Statistics are calculated

Step	#	Description
Phase is activated or refreshed	10	If data is available, phase calculates statistical data according to the **Master (bundle identifier) (SR0450.8.3)** process parameter (GID-2671956).

Prerequisite for calculation: The bundle identifier of the statistics bundle must match the bundle identifier of the respective value bundle of the referenced **Get values** phase (GID-2668003). During execution, values can only be calculated and displayed for the Measured Value data type.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.2.3 GID-2669773 Phase completion (SR0450.2.3)

- Function: Completion of phase
- Trigger: Operator confirms phase
- Postcondition: Phase is completed

Step	#	Description
Operator confirms phase	10	Phase refreshes the data automatically. ▪ If new data is available, phase displays the **Automatic refresh (SR0450.3.4.1)** information message link and remains in the active status until the operator confirms the phase again. ▪ If no new data is available, phase continues with step 20.
	20	Phase runtime data is recorded according to the **Representation in Sub-report (SR0450.5+)** layout (GID-2669770).
	30	The result of all statistical calculations is available as output variables, including those calculations that are not shown during execution and in the batch report according to the **Master (bundle identifier) (SR0450.8.3)** process parameter (GID-2671956).
	40	Phase is completed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.3 Process Parameters (SR0450.8+)

The following process parameters define the behavior of the phase.

6.3.1 Instruction Table-specific Parameters

6.3.1.1 INSTRUCTION TABLE DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Table layout	Choice list	Defines the layout of the instruction table holding the instruction texts. Available settings: **1 column**, **2 columns**, **3 columns**, **4 columns**, **5 columns**. Default setting: **1 column**.
First column narrow	Boolean	Defines if the first column of the table shall be narrow.
Show all borders	Boolean	Defines if the borders of the table shall be visible.

6.3.1.2 INSTRUCTION TABLE TEXT (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed in a column. **Restriction**: Maximum length is 2000 characters (including HTML tags).
Column 2	HTML text	
Column 3	HTML text	
Column 4	HTML text	
Column 5	HTML text	

6.3.2 Instruction Link-specific Parameters

6.3.2.1 Instruction text with links (Framework capability)

Attribute	Type	Comment
Instruction text	HTML text	Instruction text to be displayed. For any text enclosed in curly brackets you can define a hyperlink with the **Instruction link definition** process parameter (GID-2671952). Example: Refer to {SOP1270} for guidance. Maximum length is 2000 characters (including HTML tags).

6.3.2.2 Instruction link definition (Framework capability)

Attribute	Type	Comment
Link text	Text	Text to be used as link. For any text enclosed in curly brackets within the instruction text you can define a link with the **Link URL** attribute. Including the brackets in the link text is optional. Maximum length is 80 characters.
Link URL	Text	URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system. Maximum length is 256 characters.

6.3.3 Basic Parameters

6.3.3.1 GID-2671953 INSTRUCTION (SR0450.8.1)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed. **Restriction**: Maximum length is 4000 characters (including HTML tags).
Column 2	HTML text	Not used.
Column 3	HTML text	

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.3.3.2 GID-2671954 DEFINITION (SR0450.8.2)

Attribute	Type	Comment
Data collection reference	Reference	Reference to a preceding data collection phase.
Scope of data collection	Choice list	Defines the scope of collected data. Available settings: **Within operation run**, **Across operation runs**. Default setting: **Across operation runs**.
Show table in batch report	Flag	Defines if the table of values is displayed in the batch report. Default settings: **Yes** Note: The table of statistics, if applicable, is always displayed in the batch report.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.3.4 Statistics Bundle

6.3.4.1 [Statistics] Bundle process parameters ()

For the master process parameter of a bundle, its internal identifier is populated from the bundle identifier.

For all other process parameters of the bundle, their internal identifier is a concatenation of the bundle identifier and the process parameter name.

This framework capability refers to **Bundle Process Parameters (SR3146.9.7.4.1)** in "Functional Requirement Specification Recipe and Workflow Management" [A2] (GID-2668005).

6.3.4.2 GID-2671956 [Statistics] Master (Bundle identifier) (SR0450.8.3)

Attribute	Type	Comment
Show average	Flag	Defines if the average value is displayed during execution.
Show minimum	Flag	Defines if the minimum value is displayed during execution.
Show maximum	Flag	Defines if the maximum value is displayed during execution.
Show sum	Flag	Defines if the sum value is displayed during execution.
Show standard deviation	Flag	Defines if the standard deviation value is displayed during execution.

The bundle identifier of the statistics bundle must match the bundle identifier of the respective value bundle of the referenced **Get values** phase (GID-2668003).
During execution, values can only be calculated and displayed for the Measured Value data type.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.4 Exceptions (SR0450.3+)

The phase can support user-defined, user-triggered (GID-2669779), system-triggered (GID-2669778), and post-completion exceptions (GID-2669780)and their configuration by means of process parameters (GID-2668356).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

6.4.1 System-triggered Exceptions

There are no system-triggered exceptions available.

6.4.2 User-triggered Exceptions

There are no user-triggered exceptions available.

6.4.3 Post-completion Exceptions

There are no post-completion exceptions available.

6.5 Information Messages (SR0450.3.4+)

Information messages are represented in an information dialog containing a message type-specific icon, the information message, and an **OK** button.

The following information messages are available to inform the operator about how to proceed.

6.5.1 GID-2669781 Automatic refresh (SR0450.3.4.1)

UI text	Comment
Cannot confirm, since there is new data available. Values are now being refreshed automatically. Confirm again to complete the phase.	The information message is displayed upon phase completion in case new data is available. Message pack: PhaseShowValues<version> Message ID: RefreshNecessary_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.6 Questions

There are no questions available.

6.7 Decisions

There are no decisions available.

6.8 Error Messages

There are no error messages available.

6.9 Output Variables (SR0450.9+)

The following output variables are available to reference the phase's output.

6.9.1 Instance count (Framework capability)

- Data type: Long
- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.
  The count variable of a phase that has not been executed provides 0 as output value.

6.9.2 Start time (Framework capability)

- Data type: Timestamp
- Usage: The output variable provides the start time of the phase.

6.9.3 Completion time (Framework capability)

- Data type: Timestamp
- Usage: The output variable provides the completion time of the phase.

6.9.4 Identifier (Framework capability)

- Data type: String
- Usage: The output variable provides the identifier of the phase.

6.9.5 Statistics Bundle

6.9.5.1 [Statistics] Bundle output variable (Framework capability)

For all output variables of the same bundle, the output variable identifier is a concatenation of the bundle identifier and the output variable name.

This framework capability refers to **Bundle Output Variable (SR3146.9.7.4.2)** in "Functional Requirement Specification Recipe and Workflow Management" [A2] (GID-2668005).

6.9.5.2 GID-2671958 [STATISTICS] AVERAGE (SR0450.9.1)

- Data type: MeasuredValue
- Usage: The output variable provides the average value as a **MeasuredValue** object.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.9.5.3 GID-2671959 [STATISTICS] MINIMUM (SR0450.9.2)

- Data type: MeasuredValue
- Usage: The output variable provides the minimum value as a **MeasuredValue** object.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.9.5.4 GID-2671960 [STATISTICS] MAXIMUM (SR0450.9.3)

- Data type: MeasuredValue
- Usage: The output variable provides the maximum value as a **MeasuredValue** object.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.9.5.5 GID-2671961 [STATISTICS] SUM (SR0450.9.4)

- Data type: MeasuredValue
- Usage: The output variable provides the sum value as a **MeasuredValue** object.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.9.5.6 GID-2671962 [STATISTICS] STANDARD DEVIATION (SR0450.9.5)

- Data type: MeasuredValue
- Usage: The output variable provides the standard deviation value as a **MeasuredValue** object.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7 Reference Documents

The following documents are available from the Rockwell Automation Download Site.

No.	Document Title	Part Number
A1	FT PharmaSuite Functional Requirement Specification Execution Framework	PSFRSEF-RM007B-EN-E
A2	FT PharmaSuite Functional Requirement Specification Recipe and Workflow Management	PSFRSRD-RM011B-EN-E

TIP

To access the Rockwell Automation Download Site, you need to acquire a user account from Rockwell Automation Sales or Support.

8 Document Information

The document information covers various data related to the document.

8.1 Approval

This document has been approved electronically via the Rockwell Automation Document Management System (DMS). The required approvers of this document include the following:

Name	Role
Norbert Ern	Product Owner
Martin Kühne	Technical Lead
Ignaz Wangler	Test Lead

8.2 Version Information

Object	Version
FT PharmaSuite	11.01.00
Time-based Trigger	1.1
Counter-based Trigger	1.0
Get Values	11.0
Show Values	11.0
Functional Requirement Specification	1.0

9 Appendix A - Revision History

9.1 Updated Requirements

GID-2671622 Instruction (SR0440.8.1)

GID-2671868 [Measured Value] Limit configuration (SR0440.8.4)

GID-2671874 Option List editor (Framework capability)

GID-2671881 [String] Expected value configuration (SR0440.8.21)

GID-2671887 [Timestamp] Limit configuration (SR0440.8.27)

GID-2672140 [Boolean] Violation of expected value (SR0440.3.2.3)

GID-2671896 [String] Violation of expected value (SR0440.3.2.4)

GID-2671898 [Timestamp] Limit violation (SR0440.3.2.5)

GID-2671907 [String] Override value (SR0440.3.1.4)

GID-2671910 [Timestamp] Override value (SR0440.3.1.5)

GID-2671913 [Boolean] Correct value (SR0440.3.3.3)

GID-2671916 [Measured Value] Correct value (SR0440.3.3.1)

GID-2671919 [Option] Correct value (SR0440.3.3.2)

GID-2671922 [String] Correct value (SR0440.3.3.4)

GID-2671925 [Timestamp] Correct value (SR0440.3.3.5)

GID-2671940 [Timestamp] Timestamp string (SR0440.9.10)

GID-2671953 Instruction (SR0450.8.1)

9.2 Added Requirements

None

9.3 Deleted Requirements

None

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